

# The Imperative to Warn: Disentangling the “Right to Know” from the “Need to Know” about Consumer Product Hazards

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*Americans are being inundated with warnings in the labeling of consumer products. Congress, at least half a dozen federal agencies, state lawmakers, and the courts all demand that warnings accompany consumer goods. In this Article, Mr. Noah argues that there are too many decisionmakers pursuing too many different purposes, and paying too little attention to the serious information costs that may result from the overuse of warnings. In particular, he notes that indiscriminate and cumulative warnings about trivial risks may be counterproductive. Consumers either will begin to ignore product labels altogether, thereby missing other important information, or they will become alarmed by risks that were judged insufficient to warrant any more direct attempts to curtail use. Such inappropriate responses to risk labeling may outweigh the anticipated benefits of warning requirements, especially when the primary purpose of such efforts is nothing more than fulfilling an amorphous “right to know.” Thus, Mr. Noah concludes that there is a pressing need for a more coherent risk communication strategy. Without one, he argues, manufacturers of consumer products will continue to face increasing and sometimes inconsistent demands to include warnings in labeling, even if the net effect of those warnings is public apathy and confusion.*

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## Introduction

American consumers are being inundated with warnings. Hazard statements on product labels have become so commonplace that many consumers no longer notice their presence. For purposes of this Article, the term “warning” encompasses any explicit statement concerning the risks that a person may encounter when using a product. Risk information may be presented as a “Warning” or introduced by some other signal word such as “Danger” or “Caution,” and it usually describes potential health hazards to the immediate consumer. The majority of warning statements appear in product labeling but there are a number of other methods available for communicating risk information to consumers. Indeed, a fundamental question for legislators, regulators, and the courts is whether the traditional warning label requirement represents the most appropriate mechanism for conveying information about hazards posed by consumer products.

Almost no category of products has escaped the imperative to warn. Warning labels are required for cigarettes, alcoholic beverages, cosmetics, food products, pharmaceuticals, medical devices, household cleaners, and pesticides. Frequently, several different warning statements must appear in the labeling that accompanies such products; these statements may range from concrete directions for avoiding acute hazards to vague disclaimers concerning possible chronic risks. As labels become increasingly crowded, risk information is often presented in exaggerated terms in an effort to attract the attention of distracted consumers, even though the overuse of warnings may dilute the impact of truly important cautionary information or cause consumers to overreact to information about inconsequential risks.

Several factors account for the proliferation of warnings. First, legislators at both the federal and state level have demanded that the public be alerted to hazards associated with consumer products. In some cases, legislators have required warnings on specific products, often because their popularity makes more stringent agency proposals, such as outright prohibitions, politically

difficult. In most instances, however, Congress has enacted broadly worded statutes that delegate this responsibility to administrative agencies.

Agencies entrusted with the task of identifying consumer product risks and drafting appropriate precautionary language face problems other than political expediency. The identification of hazards associated with consumer products is often complicated, particularly when the hazards are chronic health risks such as cancer. In addition, it is difficult for agencies to maintain consistency in the content and format of label warnings for the products that they regulate. Even when an agency is internally consistent, it often fails to coordinate its actions with other agencies.

For their part, state lawmakers have imposed a variety of warning requirements in instances where they believe that federal regulators have not been sufficiently aggressive. Thus, states have mandated warnings on myriad products viewed as posing important health risks. In addition, some states have considered or enacted sweeping right-to-know initiatives applicable to a broad range of products. The State of California, for instance, requires that any products containing a chemical suspected of causing cancer or birth defects bear an alarming warning statement to that effect. Instead of serving as a mechanism for improving consumers' decisionmaking, such rules simply stigmatize products, perhaps in a veiled attempt to pressure companies into reformulating these products.

Finally, in products liability cases, courts have created incentives to warn for all sorts of risks, some of them trivial. When viewed with the benefit of hindsight, and without the need to consider all of the other equally trivial risks that also might be highlighted, the labeling of almost any product can be faulted. Several commentators have described the significant and often misguided influence of courts in this respect, but they generally have failed to place the judiciary's indirect role in context with the more direct and often competing warning requirements imposed by Congress, federal agencies, and state lawmakers. Indeed, it is the confluence of these four forces, rather than any one in particular, that accounts for the many problems encountered with the overuse of warning statements on product labels.

Whatever the cause, warnings have become a preferred strategy for dealing with product risks. In many instances, reliance on risk labeling may represent a perfectly sensible strategy. Increasingly, however, recourse to warning labels represents an inappropriate response to the potential hazards of consumer products. Labeling requirements frequently are justified as inexpensive alternatives to more burdensome design requirements or outright prohibitions. This premise fails to appreciate the substantial costs associated with the overuse of warnings, particularly the twin dangers of diluting the impact of more serious warnings and prompting counterproductive consumer behavior in response to overly alarming warnings about relatively insignificant risks.

In this context, dilution refers to the risk that additional warnings about relatively inconsequential hazards may cause consumers to become less attentive to labels as a whole, including some important aspects of labeling such as directions for proper use. Overreaction is a complementary problem, meaning that consumers may become preoccupied with information about trivial hazards. For instance, consumers may forego use of net beneficial products in response to warning statements, or may shift to equally beneficial substitutes that actually pose greater (though perhaps less alarming) risks. These and other considerations counsel in favor of the judicious use of warnings in the labeling of consumer products.

Ideally, warning statements should be reserved for those risks that can best be minimized by conveying information through labeling, namely by providing instructions for avoiding acute hazards. Information about other types of hazards can be disseminated through mechanisms other than explicit warning statements in labeling. Simple ingredient disclosures, for instance, may alert persons who are allergic to particular substances. Public education campaigns can describe poorly understood chronic hazards that may be associated with certain products. If a risk is in fact trivial, no information need be provided. On the other hand, if a risk becomes sufficiently serious relative to the benefits provided by a product, an outright prohibition or other design requirement might be preferable to the disclosure of information. At present, however, warning statements often are mandated in situations where either more or less stringent regulatory alternatives would seem more appropriate.

Even if decisionmakers recognize the need for greater selectivity in choosing those hazards that merit attention in product labeling, they will have to exercise more care in designing effective risk statements. It is essential, for instance, that warning statements (1) be introduced with signal words commensurate with the degree of risk posed by a product, (2) accurately specify the nature of the hazard, (3) be comprehensible to users of the product, (4) describe the degree of uncertainty underlying the risk estimate, and (5) explain how to avoid the risk. Signal words should be consistent with the degree of risk reflected in the text of the precautionary statement, which in turn should accurately convey the nature of the hazard posed by a product. Although difficulties with comprehension will necessarily limit the amount of detail that can be provided, risk statements that are exaggerated, oversimplified, or vague will not improve consumer decisionmaking. Warning statements in the labeling of consumer products should convey only concrete and actionable information about significant risks to users. Unfortunately, in addition to their lack of selectivity in identifying hazards for which warnings are appropriate, decisionmakers appear to give insufficient attention to these important considerations. Unless used in a consistent and thoughtful manner, warning statements will fail to fulfill their intended purposes.

Finally, decisionmakers must stop competing with one another for control over product labeling. The United States Congress, a number of federal agencies, state lawmakers, and the courts often work at cross-purposes in this area, accentuating the difficulties in both the identification of hazards for which warnings are appropriate and the design of effective warning statements concerning those hazards. This Article concludes that primary authority over risk labeling for consumer products should reside with federal regulators. In general, Congress should leave agencies to make the difficult judgments about appropriate responses to newly discovered hazards; it also should ensure that these decisions preempt inconsistent state and judicial requirements. For their part, federal regulators should strive for greater intra- and interagency consistency than exists today. Under this system, states would retain the power to impose warning requirements for consumer products not subject to federal regulation, and courts could entertain products liability claims in cases where manufacturers fail to comply with federal or state requirements, but neither the states nor the courts would be allowed to undermine agency labeling decisions.

The first three Parts of this Article examine the rich and varied array of warning requirements imposed or encouraged by Congress, federal administrative agencies, state governments, and the courts. Although federal agencies traditionally have been given primary responsibility in this area, Congress has intervened in several politically sensitive situations, states increasingly are imposing their own sometimes more stringent requirements, and the courts have routinely ignored the relevance of requirements imposed by the other decisionmakers. In Part IV, the Article evaluates issues that are common to these diverse warning efforts, including problems encountered in constructing appropriate messages to convey risk information to consumers. Lastly, in Part V the Article highlights the pitfalls of overreliance on warnings and suggests possible alternatives.

There is a pressing need for a more coherent risk communication strategy. If none is developed, manufacturers of consumer products will continue to face increasing and sometimes inconsistent demands to include warnings in labeling, even if the net effect is public apathy and confusion.

## I. Warning Requirements Imposed by Congress

### A. *General Misbranding Prohibitions*

Many consumer goods are subject to general statutory commands that may require the inclusion of appropriate precautionary information in labeling. The Federal Food, Drug, and Cosmetic Act (FD&C Act), for instance, prohibits the adulteration and misbranding of food, drugs, medical devices, and cosmetics

before or during delivery in interstate commerce.<sup>1</sup> The Act enumerates a series of conditions that define when each of these types of products is deemed to be misbranded.<sup>2</sup> For example, a drug or medical device would be misbranded unless its labeling bears "such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users."<sup>3</sup>

More generally, in determining whether the labeling of a food, drug, device, or cosmetic is misleading, the FD&C Act specifies that consideration must be given to any "fail[ure] to reveal facts material . . . with respect to consequences which may result from the use of the article . . ."<sup>4</sup> Under these provisions, the Food and Drug Administration (FDA) enjoys broad authority to require that warning statements appear on products subject to its jurisdiction.<sup>5</sup> Examples of FDA labeling regulations will be discussed more fully in Part II of the Article.<sup>6</sup>

The FD&C Act, enacted in 1938, was not the first federal legislation to require warning statements in the labeling of consumer products. Its predecessor, the Federal Food and Drugs Act of 1906, prohibited interstate commerce in adulterated or misbranded food and drugs.<sup>7</sup> Other than requiring that the presence of certain narcotic drugs be disclosed,<sup>8</sup> however, the 1906 Act did not specifically mandate that warnings of product risks appear in labeling. Approximately twenty years later, Congress passed the Federal Caustic Poison Act, legislation requiring that the word "POISON" and directions for treatment of accidental ingestion appear on the labels of a dozen enumerated chemicals.<sup>9</sup> The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), enacted in 1947, mandated similar labeling disclosures for highly toxic chemi-

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1. Federal Food, Drug, and Cosmetic Act, ch. 675, § 301, 52 Stat. 1042 (1938) (codified as amended at 21 U.S.C. §§ 331(a)-(c) (1988)) [hereinafter FD&C Act].

2. 21 U.S.C. §§ 343 (food), 352 (drugs and devices), 362 (cosmetics) (1988).

3. *Id.* § 352(f)(2).

4. *Id.* § 321(n).

5. The United States Department of Agriculture (USDA) has primary jurisdiction over meat and poultry products. *See* Federal Meat Inspection Act (FMIA), 21 U.S.C. §§ 601-680 (1988); Poultry Products Inspection Act (PPIA), 21 U.S.C. §§ 451-470 (1988). Both statutes contain general misbranding provisions. *See id.* §§ 453(h)(12), 457(c), 601(n)(12), 607(d).

6. Indeed, much of the Article focuses on warning efforts for products subject to FDA's jurisdiction, both because FDA has authority over the vast majority of all potentially hazardous consumer products and because the Agency has a long and rich history of requiring different types of hazard statements for such products. Parallels to other agencies and other products are noted where appropriate, and many of the lessons from FDA's experiences should be generalizable.

7. Food and Drugs Act, ch. 3915, § 2, 34 Stat. 768 (1906) (superseded by the FD&C Act, *supra* note 1).

8. *Id.* § 8, 34 Stat. 770.

9. Federal Caustic Poison Act, ch. 489, § 2, 44 Stat. 1406-07 (1927). Although largely superseded by subsequent legislation, *see infra* notes 10-11, FDA regulations implementing this statute are still in force. *See* 21 C.F.R. §§ 1230.10-.16 (1993).

cals—"POISON" in red letters, accompanied by a skull-and-crossbones symbol—as well as warnings or cautions to reduce unreasonable risks associated with the use of pesticides.<sup>10</sup> These requirements currently are enforced by the Environmental Protection Agency (EPA).

Apart from the FD&C Act, one of the most broadly applicable statutes governing warning labels on consumer products is the Federal Hazardous Substances Labeling Act of 1960.<sup>11</sup> Although it excludes food, drugs, cosmetics, tobacco, pesticides, and fuel, the Act governs all substances that are toxic, corrosive, irritating, or flammable.<sup>12</sup> Precautionary information must be preceded by specified signal words: "DANGER" if a substance is extremely flammable, corrosive, or highly toxic ("POISON" must also be used in the latter case), and "WARNING" or "CAUTION" for all other substances subject to the Act. The warning statement must identify the hazard ("Flammable," or "Vapor Harmful," for example), include a description of appropriate precautionary and first-aid measures, and provide instructions for handling the product. A substance may be classified as a banned hazardous substance if the cautionary labeling required under the Act is found to be inadequate to protect public health and safety.<sup>13</sup> The Act has been amended several times to address specific hazards to children, who generally cannot be safeguarded by recourse to warning labels.<sup>14</sup>

In 1972, Congress enacted the Consumer Product Safety Act (CPSA).<sup>15</sup> The provisions of the Act apply to consumer products other than food, drugs, medical devices, cosmetics, tobacco, pesticides, and vehicles.<sup>16</sup> The Act gave

10. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), ch. 125, § 2(u), 61 Stat. 165 (1947) (codified as amended at 7 U.S.C. § 136(q)(2)(D) (1988)). The predecessor Insecticides Act of 1910 had only included general prohibitions against adulteration and misbranding. See Insecticides Act, ch. 191, §§ 1, 8, 36 Stat. 331, 333 (1910). FIFRA was substantially amended in 1972 by the Federal Environmental Pesticide Control Act, Pub. L. No. 92-516, 86 Stat. 973 (1972).

11. Federal Hazardous Substances Labeling Act, Pub. L. No. 86-613, 74 Stat. 372 (1960) (codified as amended at 15 U.S.C. §§ 1261-1273 (1988)). This statute now is designated as the Federal Hazardous Substances Act (FHSA).

12. 15 U.S.C. § 1261(f) (1988).

13. *Id.* § 1261(q)(1). The implementing agency cannot, however, classify an article as a banned hazardous substance unless it finds "that the regulation imposes the least burdensome requirement which prevents or adequately reduces the risk of injury for which the regulation is being promulgated." *Id.* § 1262-(i)(2)(C).

14. See Child Protection Act of 1966, Pub. L. No. 89-756, 80 Stat. 1303 (1966); Child Protection and Toy Safety Act of 1969, Pub. L. No. 91-113, 83 Stat. 187 (1969); Poison Prevention Packaging Act of 1970, Pub. L. No. 91-601, 84 Stat. 1670 (1970). At a minimum, the phrase "Keep out of reach of children" must be included on the label unless a product is intended for use around children and bears adequate directions for protecting children from harm. 15 U.S.C. § 1261(p)(1) (1988). An earlier law also relied on design requirements to protect children, in this case from the risk of suffocating in empty refrigerators, because a labeling requirement would have been futile. See Refrigerator Safety Act, Pub. L. No. 84-930, 70 Stat. 953 (1956) (codified at 15 U.S.C. §§ 1211-1214 (1988)).

15. Consumer Product Safety Act, Pub. L. No. 92-573, 86 Stat. 1207 (1972) (codified as amended at 15 U.S.C. §§ 2051-2081 (1988)). The Act transferred the authority to implement the Federal Hazardous Substances Act and the Poison Prevention Packaging Act from FDA to the Consumer Product Safety Commission. 15 U.S.C. § 2079(a) (1988).

16. *Id.* § 2052(a)(1).



the newly created Consumer Product Safety Commission (CPSC) the power to promulgate regulations establishing consumer product safety standards relating to performance and warning requirements.<sup>17</sup> CPSC may ban a product if it determines that there is no feasible safety standard adequate to protect the public from unreasonable risks of either acute or chronic injury.<sup>18</sup>

In short, Congress has delegated significant authority to administrative agencies to require that warning statements accompany consumer products. Pursuant to the FD&C Act's broad prohibitions against misbranding, FDA may mandate warnings for food, drugs, medical devices, and cosmetics. In FIFRA, Congress provided somewhat more detailed guidance concerning the content of warning labels for pesticides. Nonetheless, EPA enjoys significant discretion in implementing these labeling requirements, and the Agency's jurisdiction includes pesticides and similar toxic substances intended for lay use. Finally, under the CPSA and FHSA, CPSC has been charged with the responsibility for regulating the labeling of most other potentially hazardous consumer products.

## B. *Specific Products*

In addition to delegating broad authority to agencies, Congress sometimes mandates particular warning statements for certain products, especially when industry pressure and the popularity of an otherwise troublesome product makes stricter regulation politically impossible. Saccharin and tobacco are two of the best-known examples. Others include warnings for coal tar hair dyes, mandated more than half a century ago, and recent labeling requirements for alcoholic beverages and products manufactured with ozone depleting substances.

### 1. *Coal Tar Hair Dyes*

The earliest example of a specific warning requirement imposed by Congress involved coal tar hair dyes. When it enacted the FD&C Act in 1938, Congress exempted these products from the cosmetic adulteration prohibitions,

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17. *Id.* § 2056(a) (A standard could include "[r]equirements that a consumer product be marked with or accompanied by clear and adequate warnings or instructions, or requirements respecting the form of warnings or instructions."). CPSC's power is somewhat constrained, however, because the statute provides that any such requirements "shall be reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product." *Id.* Courts have interpreted this provision as requiring that the identifiable benefits of a warning requirement must outweigh the costs to the manufacturer, including costs associated with lost sales. *See, e.g., Aqua Slide 'N' Dive Corp. v. CPSC*, 569 F.2d 831, 842 (5th Cir. 1978).

18. 15 U.S.C. § 2057 (1988). CPSC must appoint Chronic Hazard Advisory Panels to advise it on the risks of cancer, birth defects, or gene mutations associated with consumer products, *id.* § 2077(a), and the Commission must request a review by a such an advisory panel before it may undertake a rulemaking related to chronic risks of a product. *Id.* § 2080(b)(1) & (2)(A). Under the FHSA, CPSC must establish a Toxicological Advisory Board "to advise the Commission on precautionary labeling for hazardous substances," *id.* § 1275(a)(1), but the Act does not require that the Board review hazards before CPSC may promulgate regulations.

provided that they conspicuously display a cautionary statement on the label.<sup>19</sup> This exemption was included after intensive lobbying by persons in the beauty salon industry who feared that the cosmetic adulteration provision in the proposed law would force FDA to ban coal tar dyes altogether.<sup>20</sup> More recently, however, new questions have arisen about the safety of coal tar hair dyes.<sup>21</sup> Unable to ban these products in light of the statutory exemption, FDA issued a regulation requiring a cancer warning on products containing one particular coal tar hair dye ingredient.<sup>22</sup> Given the exemption for coal tar hair dyes, Congress will have to amend the statute if a risk serious enough to justify an outright prohibition comes to light in the future.

## 2. Saccharin

In 1977, Congress mandated the disclosure of information concerning animal carcinogenicity in the labels of food products containing saccharin. Earlier that year, FDA had proposed banning saccharin as an ingredient in food and other products after concluding that the available animal studies demonstrated an association between this artificial sweetener and bladder cancer.<sup>23</sup> Indeed, when the Agency proposed prohibiting most uses of saccharin, the lifetime human cancer risk extrapolated from the animal data was one-in-2500.<sup>24</sup> FDA's proposal would have allowed for the marketing of saccharin as

19. 21 U.S.C. § 361(a) (1988) ("Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness."). FDA eventually issued a regulation clarifying the scope of the coal tar hair dye exemption. See 28 Fed. Reg. 6439 (1963) (later codified as 21 C.F.R. § 70.3(u) (1993)); see also *Toilet Goods Ass'n v. Finch*, 419 F.2d 21 (2d Cir. 1969) (rejecting challenge to this regulation).

20. See, e.g., *Foods, Drugs, and Cosmetics, Hearing Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 74th Cong., 1st Sess. 489-90 (1935) (statement of Clarence Goodwin, Allied Manufacturers of the Beauty and Barber Industry).

21. In the late 1970s, Congressional hearings were held to assess claims that coal tar hair dyes may be carcinogenic. See, e.g., *Safety of Hair Dyes and Cosmetic Products, Hearing before the Subcomm. on Oversight and Investigations of the House Comm. on Interstate and Foreign Commerce*, 96th Cong., 1st Sess. (1979). But see Graham A. Colditz, *Hair Dye and Cancer*, 86 J. NAT'L CANCER INST. 164 (1994).

22. 21 C.F.R. § 740.18(a) (1993) ("WARNING—Contains an ingredient that can penetrate your skin and has been determined to cause cancer in laboratory animals."); 44 Fed. Reg. 59,509, 59,510 (1979) (explaining that "FDA does not have the statutory authority to prohibit the interstate distribution of hair dyes containing 4-MMPD"). As explained below, the regulation was voluntarily stayed by the Agency after its decision was challenged in court, but the stay was associated with the insignificance of the risk rather than a claim that the Agency lacked authority to add to the statement mandated by statute. See *infra* note 68. Although the actual carcinogenic risk was insignificant by FDA's own assessments, see R. Wilson, *Risks Posed By Various Components of Hair Dyes*, 278 ARCHIVES DERMATOLOGICAL RES. 165 (1985), the Agency's response to much stronger data would have been equally limited.

23. 42 Fed. Reg. 19,996, 20,002 (1977).

24. Curtis C. Travis et al., *Cancer Risk Management: A Review of 132 Federal Regulatory Decisions*, 21 ENVTL. SCI. TECH. 415, 417 (1987); see also Richard M. Cooper, *Saccharin—Of Risk and Democracy*, 40 FOOD DRUG COSM. L.J. 34, 34 (1985); Richard A. Merrill & Michael R. Taylor, *Saccharin: A Case Study of Government Regulation of Environmental Carcinogens*, 5 VA. J. NAT. RESOURCES LAW 1, 63-69 (1985).

a nonprescription drug product so long as an appropriate cancer warning was included on the label.<sup>25</sup>

Congress intervened by placing a moratorium on FDA's proposed action,<sup>26</sup> mandating instead that the following statement appear on food product labels:

USE OF THIS PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH. THIS PRODUCT CONTAINS SACCHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS.<sup>27</sup>

This requirement applies only to food products.<sup>28</sup> The statute authorized the Agency to revise or remove by regulation these food labeling requirements if justified by new scientific information.<sup>29</sup> Notwithstanding recent studies finding that there is no significant human cancer risk associated with the use of saccharin,<sup>30</sup> FDA has not proposed any changes to the mandatory label statement. Congress has extended the moratorium against more stringent agency action several times.<sup>31</sup>

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25. 42 Fed. Reg. 19,996, 20,004 (1977) (proposing that the labeling of such products include the following "Warning: Saccharin causes bladder cancer in animals. Use of saccharin may increase your risk of cancer.").

26. Saccharin Study and Labeling Act, Pub. L. No. 95-203, 91 Stat. 1451 (1977). The Act prohibits the Agency from (1) revoking or amending any interim food additive regulations applicable to saccharin, or (2) taking any other action to prohibit or restrict the sale or distribution of saccharin or any food, drugs, or cosmetics which lawfully contain saccharin, solely on the basis of any carcinogenic or toxic effects revealed by studies available before the date of enactment. *Id.* § 3.

27. *Id.* (codified at 21 U.S.C. § 343(o)(1) (1988)). In addition, retail establishments other than restaurants that sell foods made with saccharin were required to post notices containing this statement. 21 U.S.C. § 343(p) (1988); 21 C.F.R. § 101.11 (1993). Interestingly, the use of saccharin had been restricted for much of the preceding seventy years not due to safety concerns but apparently because it posed an economic threat to the sugar industry. See Linda C. Cummings, *The Political Reality of Artificial Sweeteners*, in CONSUMING FEARS: THE POLITICS OF PRODUCT RISKS 116, 131 (Harvey M. Sapolsky ed., 1986).

28. Congress determined that the "potential health hazard posed by ingestion of saccharin from sources other than foods, for example from saccharin-containing drugs, does not warrant the imposition of statutory labeling and advertising restrictions . . ." S. REP. NO. 353, 95th Cong., 1st Sess. 11 (1977). FDA, for its part, apparently concluded that the risk presented by this use of what it once deemed an unequivocal animal carcinogen did not warrant any sort of administrative labeling requirements for drugs or cosmetics. Cf. 44 Fed. Reg. 59,909, 59,514 (1979) (suggesting that Congress' failure to extend labeling requirement to other products such as toothpastes may reflect recognition of health benefits that result from encouraging use by improving palatability).

29. 21 U.S.C. § 343(o)(2) (1988).

30. See Clifford I. Chappel, *A Review and Biological Risk Assessment of Sodium Saccharin*, 15 REG. TOXICOL. & PHARMACOL. 253 (1992); R.W. Morgan & O. Wong, *A Review of Epidemiological Studies on Artificial Sweeteners and Bladder Cancer*, 23 FOOD CHEM. TOXICOL. 529 (1985); Council on Scientific Affairs, *Saccharin: Review of Safety Issues*, 254 JAMA 2622 (1985).

31. See Pub. L. No. 96-273, 94 Stat. 536 (1980); Pub. L. No. 97-42, 95 Stat. 946 (1981); Pub. L. No. 98-22, 97 Stat. 173 (1983); Pub. L. No. 99-46, 99 Stat. 81 (1985); Pub. L. No. 100-71, 101 Stat. 431 (1987); Pub. L. No. 102-142, 105 Stat. 910 (1991) (extending moratorium until May 1, 1997). In addition, a few states have passed laws specifically authorizing the manufacture, distribution, and sale of saccharin in intrastate commerce. See, e.g., LA. REV. STAT. ANN. § 40:1059 (West 1990); OR. REV. STAT. § 689.535 (1991).

### 3. Tobacco Products

In 1965, Congress enacted the Federal Cigarette Labeling and Advertising Act.<sup>32</sup> The legislation responded to several new developments: a recommendation of the Surgeon General,<sup>33</sup> a regulation promulgated by the Federal Trade Commission (FTC),<sup>34</sup> and actions taken by several states to regulate cigarette labeling and advertising.<sup>35</sup> The 1965 Act required that all cigarette packages bear the following statement: "Caution: Cigarette Smoking May Be Hazardous to Your Health."<sup>36</sup> Within five years the law was amended to require a sterner precaution: "Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health."<sup>37</sup> Although it sounded more ominous, the 1969 warning was not appreciably clearer than the 1965 version. Neither warning made any attempt to disclose the nature or possible severity of the threat to smokers' health, much less the probability of encountering the unnamed risk.

In 1984, the law was again substantially amended.<sup>38</sup> Congress replaced the warning that had been used for over a decade with four specific and more forceful warnings:

**SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.**

**SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.**

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32. Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965).

33. REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, SMOKING AND HEALTH 33 (1964) ("Cigarette smoking is a health hazard of sufficient importance in the United States to warrant appropriate remedial action.").

34. 29 Fed. Reg. 8324, 8325 (1964) (requiring that cigarette labeling and advertising disclose "that cigarette smoking is dangerous to health and may cause death from cancer and other diseases").

35. See 111 CONG. REC. 13,900, 13,901 (1965) (statement of Senator Moss).

36. Pub. L. No. 89-92, § 4. Congress sought to ensure that the public "be adequately informed that cigarette smoking may be hazardous to health," as well as protect commerce from "diverse, nonuniform, and confusing" labeling and advertising regulations. *Id.* § 2. The Act therefore included an express federal preemption provision. *Id.* § 5 (codified as amended at 15 U.S.C. § 1334 (1988)). These preemption provisions recently were interpreted in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992), which is discussed more fully *infra* at notes 306-09 and accompanying text.

37. Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, § 2, 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. §§ 1333, 1335 (1988)) (also prohibiting any broadcast advertising of cigarettes). This legislation responded to a new FTC proposal that would have required a detailed warning that "cigarette smoking is dangerous to health and may cause death from cancer, coronary heart disease, chronic bronchitis, pulmonary emphysema, and other diseases." 34 Fed. Reg. 7917 (1969).

38. Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200 (1984) (codified at 15 U.S.C. §§ 1331-1341 (1988)).

**SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.**

**SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.**<sup>39</sup>

These warnings are to be used on a rotating basis, alternating every three months.<sup>40</sup> The 1984 amendments also directed the Secretary of Health and Human Services (HHS) to establish a public education program.<sup>41</sup>

Federal legislation regulating warning statements on cigarette packages represents an intriguing evolution from an uncertain "Caution," to a more forceful but still vague "Warning," to a series of quite detailed warning statements. One of the warnings added in 1984 even presented the information in positive terms by explaining that quitting can greatly reduce serious health risks. The source of the warning became more prominent over time (via references to the Surgeon General), as did the particular consequences that could be linked to smoking.<sup>42</sup>

Cigarettes are not the only tobacco products to receive close legislative attention. In 1986, Congress enacted the Comprehensive Smokeless Tobacco Health Education Act.<sup>43</sup> Responding to concerns that the use of chewing tobacco may cause gum disease and mouth cancer,<sup>44</sup> Congress adopted warning requirements similar to those required for cigarettes.<sup>45</sup> The FTC was given the

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39. 15 U.S.C. § 1333(a) (1988) (also requiring that these warnings appear in cigarette advertisements). Many other countries require warnings on cigarettes and other tobacco products. The European Community, for example, has directed that all such products include the general statement that "Tobacco seriously damages health," followed (on a rotating basis) by a number of specific warnings selected by member states from a list of more than 20 statements. Council Directive 92/41/EEC, 1992 O.J. (L 158) 30 (amending Directive 89/622/EEC).

40. 15 U.S.C. § 1333(c)(1) (1988). A similar rotation of warnings was proposed for alcoholic beverages, but one witness criticized this approach as "dribbl[ing] out the warnings piecemeal," and cast doubt on the effectiveness of this policy with respect to cigarettes. *Hearings Before the Subcomm. on the Consumer of the Senate Comm. on Commerce, Science, and Transportation*, 100th Cong., 2d Sess. 89 (1988) [hereinafter *Hearings*] (statement of Professor W. Kip Viscusi, George G. Allen Professor of Economics, Dept. of Economics, Duke University).

41. 15 U.S.C. § 1341(a) (1988).

42. The 1984 Act even specifies what type of lettering to use. *Id.* § 1333(b) (e.g., the introductory phrase "Surgeon General's Warning" must appear in all capital letters). By contrast, the 1965 legislation simply mandated that the warning "shall appear in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the packaged." Pub. L. No. 89-92, § 4.

43. Pub. L. No. 99-252, 100 Stat. 30 (1986) (codified at 15 U.S.C. §§ 4401-4408 (1988)).

44. See S. REP. No. 209, 99th Cong., 2d Sess. 3, 4 (1986), reprinted in 1986 U.S.C.C.A.N. 9, 10 (expressing concern that young people were using smokeless tobacco products with the misimpression that these were safe alternatives to cigarettes).

45. Packages of smokeless tobacco must include one of the following statements on a rotating basis:

WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER.

WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS.

responsibility for implementing and enforcing these requirements,<sup>46</sup> and the Act directed HHS to establish a public education program,<sup>47</sup> but Congress has not yet provided funding for these efforts to inform consumers about the health hazards associated with smokeless tobacco products.<sup>48</sup>

#### 4. *Alcoholic Beverages*

The labeling of alcoholic beverages became subject to statutory warning requirements in 1988. Unlike previous legislative efforts by which Congress had intervened at least in part to forestall more stringent administrative regulation, the Alcoholic Beverage Labeling Act of 1988<sup>49</sup> was apparently a response to growing demands for action in the absence of any administrative efforts to address the issue.<sup>50</sup> A decade earlier, the Department of Treasury's Bureau of Alcohol, Tobacco, and Firearms (BATF) had proposed to require warning labels concerning the risks of fetal alcohol syndrome,<sup>51</sup> but this proposal was abandoned the next year in favor of a public awareness campaign.<sup>52</sup>

The 1988 legislation included the finding "that the American public should be informed about the health hazards that may result from the consumption or

WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES.

15 U.S.C. § 4402(a)(1), (c)(1) (1988). In contrast to the cigarette warnings, these are not characterized as having been issued by the Surgeon General. These same warnings must appear in any advertising for smokeless tobacco products, enclosed in a special circle-and-arrow graphic design. *Id.* § 4402(a)(2), (b)(2)(B).

46. *Id.* §§ 4402(b)-(d), 4404-4405. FTC's implementing regulations appear in 16 C.F.R. pt. 307 (1993). In promulgating these regulations, the Commission rejected comments suggesting that the circle-and-arrow format required in advertisements also apply to warning statements on product labels. 51 Fed. Reg. 40,005, 40,009-10 (1986). One aspect of the FTC's original regulations, exempting advertisements appearing on utilitarian items (such as tote bags) from the warning requirements, subsequently was invalidated. *See Public Citizen v. FTC*, 869 F.2d 1541, 1554-57 (D.C. Cir. 1989); 56 Fed. Reg. 11,653 (1991).

47. 15 U.S.C. § 4401 (1988). A similar provision was added by the 1984 cigarette legislation. *See id.* § 1341(a). Increasingly, Congress is recognizing that public education campaigns provide an important supplement to labeling requirements. In 1988, for instance, Congress amended the FHSA by inserting a new section governing the labeling of art materials. Pub. L. No. 100-695, 102 Stat. 4568 (1988) (codified at 15 U.S.C.A. § 1277 (West Supp. 1993)). This provision adopts by reference a hazard labeling standard developed by the American Society for Testing and Materials, and it also directs CPSC to review that standard periodically and disseminate educational materials. *See* 59 Fed. Reg. 10,761 (1994) (to be codified at 16 C.F.R. pt. 1500) (proposed Mar. 8, 1994).

48. Jeffrey Denny, *Snuff's Tough Stuff*, WASH. POST, May 16, 1993, at C5.

49. Alcoholic Beverage Labeling Act, Pub. L. No. 100-690, tit. VIII, § 8001(a)(3), 102 Stat. 4518 (1988) (codified at 27 U.S.C.A. §§ 213-219 (West Supp. 1993)).

50. *See* SECRETARY OF HEALTH AND HUMAN SERVICES, SIXTH SPECIAL REPORT TO THE U.S. CONGRESS ON ALCOHOL AND HEALTH (1987); A.M.A. Board of Trustees Report, *Alcohol: Advertising, Counteradvertising, and Depiction in the Public Media*, 256 JAMA 1485, 1487 (1986) (recommending that "health education labels be used on all alcoholic beverage containers and in all alcoholic beverage advertising"). *See generally* Michael S. Jacobs, *The Alcoholic Beverage Labeling Act of 1988: A Critical Analysis*, 40 SYRACUSE L. REV. 1223 (1989).

51. 43 Fed. Reg. 2186 (1978).

52. 44 Fed. Reg. 8288 (1979).

abuse of alcoholic beverages," as well as Congress' "determin[ation] that it would be beneficial to provide a clear, nonconfusing reminder of such hazards . . . ."<sup>53</sup> The Act requires that the containers of all alcoholic beverages bear, in a "conspicuous and prominent place on the container," the following statement:

GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.<sup>54</sup>

Like the earlier cigarette warnings, the trailing reference to unspecified "health problems" is not particularly illuminating. The Act also created a mechanism for revisions to the warning if new scientific evidence justified such a change.<sup>55</sup> To date, BATF has not recommended to Congress any changes in the content of the warning.

#### 5. *Ozone Depleting Substances*

Most recently, as part of the Clean Air Act Amendments of 1990, Congress required that products containing ozone depleting chemicals include the following label statement:

Warning: Contains [insert name of substance], a substance which harms public health and environment by destroying ozone in the upper atmosphere.<sup>56</sup>

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53. 27 U.S.C.A. § 213 (West Supp. 1993).

54. *Id.* § 215(a). Shortly after the Act was signed, BATF issued a temporary rule applying the placement and legibility requirements it had used for the saccharin statement on alcoholic beverages. 54 Fed. Reg. 7160, 7160-61 (1989). The final rule was published a year later. 55 Fed. Reg. 5414, 5421 (1990) (codified at 27 C.F.R. pt. 16 (1993)). In the preamble to its final rule, BATF discussed a report provided by the Surgeon General which had concluded that: "the most effective labels are those which (1) are prominent with regard to other information presented on the product label, (2) are printed in large letters and contrasting colors, and (3) do not present too much information for the consumer to assimilate." *Id.* at 5415 (quoting *Review of the Research Literature on the Effects of Health Warning Labels*, at 4 (June 1987)). The Bureau also collected samples of labels from other products bearing warning statements, such as foods, over-the-counter drugs, and cigarettes. *Id.* at 5416. In testifying against the proposed warnings for alcoholic beverages, Professor Viscusi argued that warnings "intended to browbeat individuals into changing behavior rather than trying to convey new information . . . will not serve a constructive purpose." *Hearings, supra* note 40, at 88.

55. 27 U.S.C.A. § 217 (West Supp. 1993) (directing the Secretary of Treasury, after consultation with the Surgeon General, to report such new information to Congress together with specific recommendations for amendments to the warning). A bill recently was introduced to require the use of seven rotating warning messages in any alcoholic beverage advertising. H.R. 1823, 103d Cong., 1st Sess. (1993).

56. 42 U.S.C.A. § 7671j(b) (West Supp. 1993). A similar requirement applies to products manufactured with such substances. *Id.* § 7671j(d)(1).

This labeling requirement parallels those imposed by FDA and CPSC in 1977 for chlorofluorocarbon (CFC) propellants in consumer products subject to the agencies' respective jurisdictions.<sup>57</sup> As was true with these agencies' requirements, Congress sought to influence consumer purchase decisions, thereby creating an incentive for manufacturers to shift to safer alternatives more quickly than mandated under other parts of the legislation.<sup>58</sup> EPA recently issued final regulations implementing these requirements.<sup>59</sup>

### C. Summary

Thus, Congress has mandated specific warning statements for a variety of particular consumer items, in some instances to forestall more stringent agency-imposed restrictions on popular products, but also (on occasion) in the face of agency inaction or as an adjunct to a mandatory phase-out. Although administrative agencies still must exercise some judgment in implementing these requirements, the choice, content, and sometimes even format of the warning statements have been dictated by Congress. For the vast majority of consumer products, however, federal agencies retain considerable discretion in deciding whether and how to convey risk information.

## II. Warning Requirements Imposed by Federal Agencies

In implementing the general statutory misbranding prohibitions, federal agencies have mandated that cautionary statements appear in the labeling of various types of consumer products. This Part reviews the different requirements applicable to cosmetics, food and food additives, nonprescription drug products, prescription drugs, pesticides, and other household products. Although illustrative rather than exhaustive, the discussion provides the detail necessary to understand and fully appreciate the diverse strategies used for

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57. See 42 Fed. Reg. 22,018 (1977); 42 Fed. Reg. 42,780 (1977). These are discussed more fully in the next Part. See *infra* notes 76-84 and accompanying text.

58. See S. REP. NO. 228, 101st Cong., 2d Sess. 398-99 (1990), reprinted in 1990 U.S.C.C.A.N. 3781. Although the Senate Report also mentioned that the warnings would alert consumers "that they must take care in handling and disposing of such product[s] to avoid emitting such substances to the environment," the primary goal was to dissuade consumers from selecting these products in the first place. *Id.*; see also 57 Fed. Reg. 19,166, 19,169 (1992) ("The increased ability of consumers to express a preference for products not using controlled substances would create a market-based incentive for manufacturers to find and utilize substitutes for ozone-depleting substances that reduce the overall risk to human health and the environment."); Orval E. Nangle, *Stratospheric Ozone: United States Regulation of Chlorofluorocarbons*, 16 ENVTL. AFF. 531, 575-76 (1989) ("[L]abeling products containing or manufactured with CFCs and halons is inexpensive and is the least burdensome form of regulation. . . . The public has a right to know that a product contains ozone-depleting substances and a right to express a choice for or against such substances.").

59. See 40 C.F.R. §§ 82.100-82.124 (1993). This regulation is discussed more fully in the next Part. See *infra* notes 203-213 and accompanying text.



different consumer products as well as to convey a sense of the sheer immensity of federal regulations applicable to labeling.

Each product category provides important lessons about agency decisions to require warning statements in labeling. For example, in the labeling of some products, all risk information is presented as a “Warning,” while the labeling of other products uses more carefully differentiated categories for the presentation of information about potential health hazards. In some situations, agencies have addressed each new safety question by requiring an additional warning, but in other cases every effort is made to avoid the use of alarming hazard statements. For instance, ingredient labeling rather than warning requirements for food products are used to alert persons with allergies. Some warnings serve as general disclaimers of a product’s safety (especially when concerns about possible chronic hazards have arisen) while others primarily seek to convey or emphasize instructions for avoiding acute risks. Taken together, the many different examples reveal an inconsistent and sometimes incoherent patchwork of labeling requirements.

### *A. Cosmetic Products*

Cosmetics were the first consumer products for which Congress drafted a specific warning statement, and they are now subject to a series of separately issued warning regulations that present a microcosm of the different mistakes that agencies sometimes make when requiring warning labels. FDA’s numerous warning requirements for cosmetics run the gamut from generalized disclaimers that the safety of a product has not been verified to concrete instructions for avoiding immediate risks, and from statements about the possible environmental consequences attending use of a product to alarming warnings about risks of cancer extrapolated from animal studies. Despite their diverse content and purposes, these and other precautionary statements for cosmetics are all designated as “Warnings.”

FDA’s cosmetic labeling regulations set forth several required warning statements. First, cosmetic products whose safety has not been adequately substantiated must bear the following disclaimer:

*Warning*—The safety of this product has not been determined.<sup>60</sup>

Second, cosmetic products in self-pressurized containers must bear the following statement on their labels:

*Warning*—Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°, F. Keep out of reach of children.<sup>61</sup>

Third, in addition to this general warning for self-pressurized containers, cosmetic products using a halocarbon or hydrocarbon propellant must state:

*Warning*—Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.<sup>62</sup>

Fourth, a cosmetic product containing a CFC propellant must bear the following information:

*Warning*—Contains a chlorofluorocarbon that may harm the public health and environment by reducing ozone in the upper atmosphere.<sup>63</sup>

Finally, FDA generally requires that the label of a cosmetic product bear a warning statement “whenever necessary or appropriate to prevent a health hazard that may be associated with the product.”<sup>64</sup> Thus, manufacturers must determine what other warning statements may be necessary to ensure the safe use of their products.

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60. 21 C.F.R. § 740.10(a) (1993). A different disclaimer recently was proposed for certain cosmetic suntanning products: “*Warning*—This product does not contain a sunscreen and does not protect against sunburn.” 58 Fed. Reg. 28,194, 28,302 (1993) (to be codified at 21 C.F.R. § 740.19) (proposed May 12, 1993). FDA explained that, because consumers expect that tanning products will protect against sunburn, and in light of the serious consequences of overexposure to the sun, “such products could be potentially dangerous” if not accompanied by an informative labeling statement. *Id.* at 28,207. The Agency did not, however, explain why a “Warning” was necessary. The proposed requirement also would apply to cosmetic dyes marketed as “sunless” tanning products. *Id.* at 28,293-94. This is a context in which one would not expect the failure to reveal the absence of a sunscreen ingredient to be misleading.

61. 21 C.F.R. § 740.11(a)(1) (1993). CPSC requires a similar warning statement for products in self-pressurized containers, though the signal word “Caution” may be substituted for the word “Warning.” 16 C.F.R. § 1500.130(b) (1993).

62. 21 C.F.R. § 740.11(b)(1) (1993). A judicial challenge to these regulations proved unsuccessful. *See* Cosmetic, Toiletry & Fragrance Ass’n v. Schmidt, 409 F. Supp. 57 (D.D.C. 1976).

63. 21 C.F.R. § 740.11(c)(1) (1993). Many of these requirements apply to food products, nonprescription drugs, and medical devices as well. *See id.* §§ 101.17, 369.21, 801.425(a).

64. *Id.* § 740.1(a). Similarly, under a regulation originally promulgated by FDA under the FHSA before responsibility for implementing that legislation was transferred to CPSC, a cosmetic product will be considered misbranded if its label fails to bear information alerting a household to any “substantial risk of injury or illness” associated with customary or usual use of the product. 16 C.F.R. § 1500.81(a) (1993).

FDA also has mandated detailed precautionary statements for a few specific products that it regulates as cosmetics, namely feminine deodorant sprays and foaming detergent products.<sup>65</sup> FDA adopted these requirements because it had received numerous complaints of nonserious adverse reactions from customers and physicians. Although conceding that it knew of no medicinal benefits derived from these products, the Agency conceived of the labeling requirements as appropriate interim measures pending the receipt of further information.<sup>66</sup> The last warning statement for cosmetic products appearing in the regulations advised of the possible carcinogenicity of a coal tar hair dye ingredient.<sup>67</sup> FDA agreed to an ongoing stay after this rule was challenged for not considering the extremely small human risk demonstrated by the available animal data.<sup>68</sup> FDA had found no epidemiological data suggesting a risk to humans using 4-MMPD,<sup>69</sup> but it deliberately selected the signal word "Warning" for the 4-MMPD statement so as "to parallel other warnings for cosmetics that pose risks of possible grave injury, and to alert consumers to the nature of the information conveyed."<sup>70</sup>

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65. For example, the labels of feminine deodorant sprays must bear the following information:

*Caution*—For external use only. Spray at least 8 inches from skin. Do not apply to broken, irritated, or itching skin. Persistent, unusual odor or discharge may indicate conditions for which a physician should be consulted. Discontinue use immediately if rash, irritation, or discomfort develops.

21 C.F.R. § 740.12(b) (1993). A similar "Caution" concerning irritation of skin and the urinary tract from prolonged use is required for foaming detergent (bubble bath) products unless clearly labeled for use exclusively by adults. *Id.* § 740.17(b). An earlier version of the regulation, which applied to all products irrespective of user population, was stayed by FDA. 48 Fed. Reg. 7169 (1983). Data over a 10 year period revealed less than two adverse reactions per million units distributed. 51 Fed. Reg. 20,471, 20,472 (1986).

66. *See, e.g.*, 38 Fed. Reg. 16,236 (1973) ("Although the reported reactions are not sufficiently great to justify removal of these products from the market, they are sufficient to justify required warnings. . . . Until further information can be developed concerning the safety of these sprays, appropriate label warnings to minimize consumer risk should be required."). In the preamble to its final regulation, FDA reiterated this point. 40 Fed. Reg. 8926 (1975). The regulation requiring warnings on products in self-pressurized containers was based on a similar rationale. *See* 40 Fed. Reg. 8912, 8913 (1975) ("[A]t this time there is not sufficient scientific data demonstrating a degree of health hazard to justify a total ban on all aerosol products.").

67. 21 C.F.R. § 740.18(a) (1993) ("WARNING: Contains an ingredient that can penetrate your skin and has been determined to cause cancer in laboratory animals."). The 1978 proposal was based on the results of a bioassay showing significant increases in various animal cancers. 43 Fed. Reg. 1101, 1102 (1978) ("The NCI study firmly establishes that [4-MMPD] is carcinogenic in two rodent species.").

68. *Carson Products Co. v. Department of Health & Human Services*, Food Drug Cosm. L. Rep. (CCH) ¶ 38,071 (S.D. Ga. 1980). FDA thereupon stayed the regulation, 47 Fed. Reg. 7829 (1982), and it has not reopened the matter since that time. FDA is not alone in having experienced difficulties in assessing the human health risks of potential carcinogens. *See Gulf South Insulation v. CPSC*, 701 F.2d 1137, 1147 n.20 (5th Cir. 1983) (describing interagency inconsistencies with regard to formaldehyde); 50 Fed. Reg. 10,372 (1985) (interagency report on risk assessment).

69. In explaining the basis for the final regulation requiring a warning on products containing 4-MMPD, FDA took the position that "[t]he demonstration that a compound causes cancer in animals must be taken as evidence that it has a potential for causing cancer in humans, unless there is strong evidence to the contrary." 44 Fed. Reg. 59,509, 59,516 (1979).

70. *Id.* at 59,516. FDA explained, however, that it would have banned 4-MMPD rather than require a warning statement were it not for the statutory provision governing coal tar hair dyes. *Id.* at 59,511.

Set out in less than three pages of the Code of Federal Regulations, FDA's labeling requirements for cosmetics illustrate several mistakes often encountered with warning strategies. First, the regulations mandate numerous and arguably too many warning statements. Theoretically, a single product could be required to carry half a dozen separate warnings. The consequences of overwarning are described at length in Part V(B) of this Article. Second, notwithstanding the differing types and seriousness of the risks disclosed in these label statements, most are designated as "Warnings." The problems with such an undifferentiated approach will be discussed more fully in Part IV(A). Third, the Agency adopted a warning strategy in some cases to disclose risk information and to provide instructions for minimizing those risks, but in other cases FDA chose this approach precisely because it felt that there was inadequate risk information on which to base either more or less stringent regulatory requirements. Indeed, the disclaimer that the safety of a product had not been determined may have been mandated by the Agency to pressure cosmetic manufacturers to undertake safety testing of all ingredients used in their products, rather than provide consumers with any risk information.

The most notable failing of the cosmetic warning regulations is the Agency's pursuit of different and sometimes inconsistent goals. As more fully explained in subsequent sections of this Article, "Warning" statements in the labeling of consumer products ideally should convey concrete and actionable information about significant risks to consumers. From this perspective, the general cosmetic labeling requirement, mandating a warning statement "whenever necessary or appropriate *to prevent a health hazard* that may be associated with the product,"<sup>71</sup> makes the most sense but provides the least clear guidance to regulated entities. The warning required for cosmetics containing halocarbon or hydrocarbon propellants, advising that intentional misuse can be harmful, more closely approaches the ideal and represents a reasonable means of deterring hazardous behavior.<sup>72</sup> The warning for cosmetics in self-pressurized containers provides a series of instructions without specifying the consequences of inappropriate use. This warning more closely resembles the "Caution" statements mandated for feminine deodorant sprays and foaming detergent bath products, but the specificity of FDA's precautionary directions is laudable whatever signal word is used. By contrast, the disclaimer for untested products does not provide consumers with any guidance for how to respond to such information, much less specify the risks that may be encountered in choosing

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71. 21 C.F.R. § 740.1(a) (1993) (emphasis added).

72. In the preamble to the final rule, FDA explained that it selected the warning because "it is precise in its description of the conditions of misuse." 40 Fed. Reg. 8912, 8914 (1975) (rejecting alternative warning "Do not inhale directly, deliberate inhalation of contents can cause death."). It should be noted, however, that misuse warnings may encourage rather than deter risk-taking behavior, an argument FDA consistently has rejected. See *infra* notes 476-478 and accompanying text.

to use the product, and the stayed 4-MMPD warning presents an accurate but incomplete statement that fails to quantify the approximate human cancer risk.

The CFC warning, although it does indicate the consequences of use, is wholly unrelated to protecting the immediate user from any hazards. Instead, the warning for products containing CFC propellants sought to foster environmentally desirable consumer choices.<sup>73</sup> The National Academy of Sciences (NAS) issued a report in 1976 that included a recommendation for “informative labeling” of products containing CFCs.<sup>74</sup> EPA was the first agency to issue a labeling requirement, demanding that all pesticides prominently display the following statement on the front panel of the label: “This Product Contains Chlorofluorocarbon-11 (or -12, as appropriate).”<sup>75</sup> FDA followed with a “Warning” statement (“Contains a chlorofluorocarbon that may harm the public health and environment by reducing ozone in the upper atmosphere.”) applicable to cosmetics and all other products that it regulates.<sup>76</sup> In issuing its final rule, the Agency rejected a comment objecting to the inconsistency between EPA’s simple disclosure statement and FDA’s warning requirement.<sup>77</sup> Shortly thereafter, CPSC required a warning statement in the labeling of products subject to its jurisdiction, using language that was identical to the warning mandated by FDA.<sup>78</sup>

All three agencies viewed their respective requirements as short-term measures that could be implemented with relative ease pending the planned phase-out of CFC propellants. FDA explained that “[a]n appropriate warning statement will encourage self-restraint by consumers and encourage them to find alternative products . . . during the interim period.”<sup>79</sup> These warning requirements also were tailored to avoid unnecessarily alarming consumers in cases where the use of products containing CFC propellants may be beneficial. FDA took care to phrase its warning so as to “minimize[ ] any possibility that the consumer will believe that the warning refers to risks of harm from direct inhalation of the products,” and it also exempted prescription drugs and other products that require CFCs, such as medical devices used for treating asthma, because “[t]he presence of the warning label might confuse consumers and dissuade them from purchasing a product that provides a health benefit.”<sup>80</sup> FDA

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73. See 41 Fed. Reg. 52,071, 52,074-75 (1976).

74. NAS, *Halocarbons: Environmental Effects of Chlorofluoromethane Release* (1976), reprinted in F-D-C REPORTS, Sept. 20, 1976, at 12, 15.

75. 42 Fed. Reg. 9205 (1977).

76. 21 C.F.R. §§ 101.17(c), 369.21, 740.11(c)(1), 801.425(a) (1993).

77. 42 Fed. Reg. 22,019, 22,020 (1977) (“All three agencies have recognized the suitability of imposing some type of labeling requirement, but they have differed in their approach to the text and the applicability of the requirement, in part because of reasons of policy, and in part because of differences in the type of products they regulate.”).

78. 16 C.F.R. § 1401.5(a) (1993).

79. 41 Fed. Reg. 52,071, 52,075 (1976); see also 42 Fed. Reg. 22,019, 22,026 (1977).

80. 41 Fed. Reg. 52,071, 52,075 (1976).

soon thereafter prohibited all non-essential uses of CFC propellants in prescription drugs as well as in other products.<sup>81</sup> Especially now that EPA is poised to phase out most other uses of any ozone depleting substances, the CFC regulations are primarily of historical relevance.

The FDA and CPSC decisions to frame their labeling statements as "Warnings" are questionable given the admitted absence of any direct risk to the user of a product containing CFC propellants. FDA took the position that "consumer[s] should be alerted to all the serious hazards posed by a product."<sup>82</sup> In pursuit of such a broad goal, however, agencies might require warnings for numerous products that may contribute to environmental degradation and thereby threaten public health in the future (e.g., products in nonrecyclable packaging). By comparison, in the same year that it mandated the CFC warning, FDA decided that the possible adverse environmental effects of its decision to approve the use of plastic beverage containers were not of sufficient magnitude to justify any limitations on their use.<sup>83</sup> Perhaps public education campaigns should be used in instances where consumers need to understand the environmental consequences of their choices, but statements on product labels designated as "Warnings" and given the same prominence as directions against the more serious and immediate health hazards such as those posed by inhalation are not appropriate in such circumstances.<sup>84</sup>

The apparent shortcomings of FDA's cosmetic labeling regulations may have arisen because of a gradual accretion of separately promulgated rules rather than a single decision to impose these varied and numerous requirements. But in any case the Agency clearly believed that warnings could properly serve a number of different purposes. Notwithstanding the Agency's reassurances that it had considered the problem of requiring too many different and dissimilar

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81. 21 C.F.R. § 2.125(c) (1993); 43 Fed. Reg. 11,301 (1978). Although this prohibition made the warning requirement obsolete in most cases, certain essential uses are still permitted, 21 C.F.R. § 2.125(e) (1993), but are not exempt from the warning requirement which remains in effect. *Id.* §§ 369.21, 801.425; see also 58 Fed. Reg. 34,812, 34,812-13 (1993) (explaining that warning requirement remains in effect for limited class of products); 43 Fed. Reg. 11,301, 11,311-15 (1978) (expanding list of essential uses exempt from prohibition without also revising uses exempt from warning requirement); M-D-D-I REPORTS ("The Gray Sheet"), Oct. 4, 1993, at 18 (reporting FDA may further expand list of essential uses).

82. 42 Fed. Reg. 22,019, 22,026-27 (1977).

83. 42 Fed. Reg. 9227, 9229-30 (1977). Two years earlier FDA had revised its NEPA regulations to clarify that the Agency could not take adverse environmental effects into account when regulating products, explaining, for instance, that it cannot refuse to approve or withdraw approval of a safe food additive or drug "if the product would only contribute to litter or deplete the nation's energy resources or detract from scenic beauty." 40 Fed. Reg. 16,662 (1975). After the regulation was challenged successfully, *Environmental Defense Fund, Inc. v. Mathews*, 410 F. Supp. 336, 338 (D.D.C. 1976), FDA decided to acquiesce in the court's decision and revoke this rule. 41 Fed. Reg. 21,768 (1976).

84. To its credit, FDA did not mandate that the CFC warning appear in large type because it concluded that this "would distract attention from other equally important warnings and information." 42 Fed. Reg. 22,019, 22,027 (1977). More recently, the Agency drafted alternative language for prescription and nonprescription drugs and devices containing or manufactured with ozone depleting substances so that persons will be able "to appreciate environmental concerns" without creating undue alarm. 58 Fed. Reg. 34,812, 34,813-14 (1993).

warnings,<sup>85</sup> FDA simply tacked on one labeling requirement after another as the need arose without fully considering the cumulative impact of the regulations. The net effect is a somewhat incoherent patchwork of cautionary labeling requirements. As explained in the sections that follow, some of these same problems arise with respect to other consumer products, but FDA and the other agencies responsible for the regulation of labeling have responded to these difficulties differently in each case.

## B. *Foods and Food Additives*

FDA has mandated relatively few warnings for food products.<sup>86</sup> Other than the various warning statements prescribed for food products packaged in self-pressurized containers, statements which are identical to those required for cosmetic products,<sup>87</sup> FDA has required explicit warnings for only one food product category.<sup>88</sup> Although food product warnings are uncommon, FDA sometimes designs food labeling regulations to provide indirect warnings of

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85. See, e.g., 42 Fed. Reg. 22,019, 22,027 (1977) ("While the impact of warnings might be reduced if numerous statements were included, the Commissioner concludes that the warnings on self-pressurized containers are not so numerous as to make the dilution effect an overriding concern at this time."). CPSC similarly concluded that "the warnings on self-pressurized containers are not so numerous that the additional warning would substantially dilute the effectiveness of other warnings that may be required on products to alert consumers to even greater hazards." 42 Fed. Reg. 42,780, 42,782 (1977).

86. As explained above, USDA shares jurisdiction with FDA over food products containing meat and poultry. See *supra* note 5. USDA generally has not required that any cautionary statements appear in the labeling of such products. See 9 C.F.R. pt. 317 (1993) (general labeling requirements for meat products); *id.* pt. 381(N) (labeling requirements for poultry products). In response to recent food poisonings traced to contaminated hamburgers, and as part of a settlement reached with consumer groups that had sued the Agency, USDA mandated that safe handling instructions appear in labeling. See 58 Fed. Reg. 52,856 (1993) (to be codified at 9 C.F.R. pts. 317, 381). Although the Agency declined to require explicit "warnings" as some had suggested, *id.* at 52,868, the new labeling rules mandate inclusion of the following "rationale" statement: "Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly." *Id.* at 52,872. After it was invalidated on procedural grounds, USDA repromulgated the same regulation. 59 Fed. Reg. 14,528, 14,530 (1994) (to be codified at 9 C.F.R. pts. 317, 381).

87. 21 C.F.R. § 101.17(a)-(c) (1993). In a related requirement, decorative ceramicware must be labeled as "not for food use" because of the risk of lead poisoning. 59 Fed. Reg. 1638, 1641 (1994) (to be codified at 21 C.F.R. § 109.16(b)(1)).

88. Low-calorie protein products for rapid weight loss must bear the following statement:

WARNING: Very low calorie protein diets (below 400 Calories per day) may cause serious illness or death. Do Not Use for Weight Reduction in Such Diets Without Medical Supervision. Not for use by infants, children, or pregnant or nursing women.

21 C.F.R. § 101.17(d)(1) (1993). Protein products advertised for use in nutritionally balanced diets providing 400 or more calories per day must bear a milder "Notice." *Id.* § 101.17(d)(2). FDA's original regulation had used 800 calories as the threshold and mandated a "Warning" even above that threshold. See 45 Fed. Reg. 22,904, 22,914 (1980). After a pair of judicial challenges, FDA amended the regulation. 49 Fed. Reg. 13,679, 13,690 (1984). The new regulation was upheld against subsequent challenges. See *National Nutritional Foods Ass'n v. Novitch*, 589 F. Supp. 798, 800-01 (S.D.N.Y. 1984); *National Nutritional Foods Ass'n v. Young*, 598 F. Supp. 1107, 1108 (S.D.N.Y. 1984).

potential health hazards. For instance, mandatory ingredient labeling alerts consumers to the presence of substances to which they might be allergic.<sup>89</sup>

General ingredient labeling requirements may not, however, describe particular components in sufficient detail for allergic consumers, so FDA has imposed special disclosure requirements in certain cases. "The agency's primary tool for handling a situation where population subgroups may be at increased risk from a food ingredient that is safe for most people is to use [ingredient] labeling to inform those persons who need or want to avoid the ingredient."<sup>90</sup> Thus, food product labeling must disclose the presence of substances such as the color additive FD&C Yellow No. 5<sup>91</sup> and sulfiting agents used as preservatives.<sup>92</sup> In addition, FDA regulations governing the use of certain food additives sometimes mandate the disclosure of possible side effects from consumption<sup>93</sup> or cautionary information applicable to particularly vulnerable groups.<sup>94</sup>

Products that may trigger allergic reactions provide one of the best justifications for product labeling. In the case of Yellow No. 5, FDA found evidence of a causal link between the color additive and serious allergic reactions in susceptible individuals.<sup>95</sup> The Agency rejected comments urging it to ban Yellow No. 5, explaining that "the requirement for a label declaration as opposed to a possible prohibition against the use of the color has been selected because it minimizes the societal impact while providing an adequate

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89. 56 Fed. Reg. 28,592, 28,615 (1991) ("[T]he information present in the ingredient list is adequate to enable the consumer to avoid ingredients of concern."). Allergic responses to common foods can be quite serious, especially for children. See Hugh A. Sampson et al., *Fatal and Near-Fatal Anaphylactic Reactions to Food in Children and Adolescents*, 327 NEW ENG. J. MED. 380 (1992). In addition to its programs to monitor for microbial contamination of food, FDA has created an adverse reaction reporting system similar to that used for drugs. See Linda Tollefson, *Monitoring Adverse Reactions to Food Additives in the U.S. Food and Drug Administration*, 8 REG. TOXICOL. & PHARMACOL. 438, 441 (1988) (noting that majority of initial reports concerned sulfiting agents and aspartame).

90. 58 Fed. Reg. 24,314 (1993).

91. 21 C.F.R. § 74.705(d)(2) (1993). A comparable requirement applies to drugs containing Yellow No. 5. *Id.* §§ 74.1705(c)(3), 201.20(a). BATF has imposed similar requirements for alcoholic beverages. See 27 C.F.R. §§ 4.32(c), 5.32(b)(5), 7.22(b)(4) (1993).

92. 21 C.F.R. §§ 101.100(a)(4), 130.9 (1993). By comparison, prescription drugs must include a "warning" statement about sulfiting agents in labeling. 21 C.F.R. § 201.22(b) (1993).

93. See 21 C.F.R. § 184.1835(e) (1993) ("The label and labeling of food whose reasonably foreseeable consumption may result in a daily ingestion of 50 grams of sorbitol shall bear the statement: 'Excess consumption may have a laxative effect.'"); *id.* § 180.25(e) (same requirement for mannitol).

94. See *id.* § 172.804(e)(2) (food containing aspartame must bear following statement: "PHENYLKETONURICS: CONTAINS PHENYLALANINE."). This same statement is required in the labeling of drug products containing aspartame. *Id.* § 201.21. BATF recently imposed this requirement on malt beverages. 58 Fed. Reg. 44,131, 44,132 (1993) (to be codified at 27 C.F.R. pt. 7).

95. 42 Fed. Reg. 6835, 6836 (1977). FDA sought comments on the possibility of banning the use of Yellow No. 5 in certain classes of ingested drugs, *id.* at 6837-38, but evidently it never seriously considered prohibiting the use of this color additive in food. Although there was little evidence of allergic reactions in humans, FDA also promulgated regulations requiring labeling disclosures of Yellow No. 6 because of its structural similarity to Yellow No. 5 as well as suggestive animal evidence. 51 Fed. Reg. 41,765, 41,779 (1986); 52 Fed. Reg. 21,505, 21,506-07 (1987). After a judicial challenge was filed, FDA withdrew the requirement. 53 Fed. Reg. 49,138 (1988).



measure of protection for those sensitive to the color.”<sup>96</sup> In the case of sulfiting agents, FDA did prohibit uses of these additives where labeling would be impractical (e.g., raw produce).<sup>97</sup> For packaged foods, however, the Agency opted for a simple ingredient declaration on the label, rejecting comments urging that a “Warning” be required.<sup>98</sup> FDA’s recent and wide-ranging revisions of its food labeling regulations will provide even more detailed ingredient information of possible relevance for persons with allergies,<sup>99</sup> but the Agency again rejected suggestions that explicit allergy “Warnings” appear on product labels.<sup>100</sup>

FDA has taken the position that warnings on food products are appropriate only when based on sound scientific data with clear application to human health, stating that it “is unwilling to require a warning statement in the absence of clear evidence of a hazard.”<sup>101</sup> The Agency recently reiterated its position, explaining that it “does not intend to require warning statements [on food labels] except in specific instances where there is scientifically based evidence

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96. 44 Fed. Reg. 37,212, 37,214 (1979) (adding, however, that it would reconsider proposals for a ban if labeling requirements prove inadequate). FDA retreated from its proposal to mandate that a warning statement appear in the labeling of over-the-counter (OTC) and prescription drugs in view of the fact that it was only requiring an ingredient declaration on food labels. *Id.* at 37,217. The package insert for prescription drugs must, however, include the following statement in the “Precautions” section:

This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

21 C.F.R. § 201.20(b) (1993); *see also* 45 Fed. Reg. 60,419, 60,421 (1980) (rejecting comment arguing statement was redundant with ingredient declaration).

97. 51 Fed. Reg. 25,012, 25,012-13 (1986) (“labeling alone will not always provide adequate protection for sulfite-sensitive individuals”); *see also* Allen v. Delchamps, Inc., 624 So. 2d 1065, 1066-67 (Ala. 1993) (grocer could be held liable for customer’s anaphylactic reaction to sulfite used on fresh produce in violation of FDA regulation).

98. 51 Fed. Reg. 25,012, 25,013 (1986); *see also* 50 Fed. Reg. 13,306, 13,306 (1985) (in proposing regulation, FDA explained that “a label declaration of sulfites will enable persons intolerant to sulfites to minimize their exposure to these ingredients”). In extending this ingredient declaration requirement to standardized foods, the Agency repeated its earlier conclusion that, notwithstanding the fact that sulfites “are one of the few food ingredients known to cause anaphylactic shock and death,” it is not “necessary to require a warning statement on food labels or to ban all uses of sulfites.” 58 Fed. Reg. 2850, 2855-56 (1993).

99. *See, e.g.*, 58 Fed. Reg. 2876 (1993) (to be codified at 21 C.F.R. § 101.4(d)) (when used in food products represented as “nondairy,” caseinate will have to be described as “(a milk derivative)”). This requirement seeks to address the sort of problems identified by James E. Germ et al., *Allergic Reactions to Milk-Contaminated “Nondairy” Products*, 324 NEW ENG. J. MED. 976 (1991).

100. 58 Fed. Reg. 2850, 2872 (1993) (declining “to require warnings for ingredients that only cause mild idiosyncratic responses”). FDA has rejected suggestions that all bioengineered foods disclose their origin, but it would require disclosure if a risk of allergenicity has been introduced by the insertion of genetic material from another source. *See* 58 Fed. Reg. 25,837, 25,840 (1993); 57 Fed. Reg. 22,984, 22,991 (1992) (“For example, if a tomato has had a peanut protein introduced into it and there is insufficient information to demonstrate that the introduced protein could not cause an allergic reaction . . . , a label declaration would be required to alert consumers who are allergic to peanuts so they could avoid that tomato . . .”).

101. 56 Fed. Reg. 28,592, 28,615 (1991).

of a potential health hazard."<sup>102</sup> Some food products and additives have been associated with chronic hazards, and it is well recognized that potential carcinogens are ubiquitous in the human diet.<sup>103</sup> Some occur naturally, and others are introduced during processing, but FDA has never suggested that every food product containing a suspected carcinogen should bear a warning statement.

[A] requirement for warnings on all foods that may contain an inherent carcinogenic ingredient or a carcinogenic contaminant . . . would apply to many, perhaps most foods in a supermarket. Such warnings would be so numerous they would confuse the public, would not promote informed consumer decisionmaking, and would not advance the public health.<sup>104</sup>

If a chronic risk appears to be serious, FDA will prohibit use of the food or food additive (as it had proposed to do with saccharin) rather than require a label warning.<sup>105</sup> Some commentators have objected, however, that such a policy unduly limits consumer freedom of choice.<sup>106</sup>

Oftentimes, animal bioassays provide only equivocal results of doubtful application to humans. Even studies suggestive of significant carcinogenic activity generally are not relied upon without a close assessment of the weight of the evidence.<sup>107</sup> Extrapolating the results of high dose animal studies to humans creates reason for caution; it is possible that observed tumors arise only

102. 58 Fed. Reg. 2850, 2872 (1993).

103. 52 Fed. Reg. 5081, 5083 (1987) ("[E]ven some human nutrients—such as selenium, chromium, and nickel—when isolated and administered to laboratory animals in the enormous quantities represented by the maximum tolerated dose, have been found to be carcinogenic."); see also 58 Fed. Reg. 33,690, 33,694 (1993) (same); Bruce N. Ames et al., *Ranking Possible Carcinogenic Hazards*, 236 SCIENCE 271, 277 (1987).

104. 44 Fed. Reg. 59,509, 59,513 (1979).

105. See 42 Fed. Reg. 52,814, 52,814 (1977) (rejecting suggestion that labels of contaminated food products bear warning because "[i]f any food is found to be hazardous to health, FDA will not permit it to be distributed"); see also Richard M. Cooper, *Freedom of Choice in the Real World*, 34 FOOD DRUG COSM. L.J. 612, 622-23 (1979) (defending FDA policy of regulating hazards in food through prohibitions rather than warnings).

106. See Peter Barton Hutt, *Public Policy Issues in Regulating Carcinogens in Food*, 33 FOOD DRUG COSM. L.J. 541, 556 (1978); Peter Barton Hutt, *The Basis and Purpose of Government Regulation of Adulteration and Misbranding of Food*, 33 FOOD DRUG COSM. L.J. 505, 537-39 (1978) (arguing that risk labeling may be appropriate whenever outright prohibition would restrict consumer freedom of choice); Note, *Health Regulation of Naturally Hazardous Foods: The FDA Ban on Swordfish*, 85 HARV. L. REV. 1025, 1041, 1044-46 (1972) (arguing that labeling requirement would have been more appropriate than FDA's strict limits on mercury contamination of fish).

107. See 52 Fed. Reg. 49,572, 49,577 (1987) Even when risk assessments have been performed, the use of conservative assumptions at each step in the calculation tends to dramatically overstate risks. See OMB, *Regulatory Program of the United States Government* xxv (1987) ("The final risk estimate derived from these compounded conservative assumptions may be more than a million times greater than the best estimate and may, thus, have a probability of being accurate that is virtually zero."); Albert L. Nichols & Richard J. Zeckhauser, *The Perils of Prudence: How Conservative Risk Assessments Distort Regulation*, 8 REG. TOXICOL. & PHARMACOL. 61, 67 (1988).

because of tissue damage caused by the near lethal quantities of a substance used in test animals. Thus, FDA has allowed the use of numerous substances that appear to cause tumors only in high dose animals, and in no case has the Agency demanded chronic risk disclosures in labeling.<sup>108</sup>

Although exaggerated intakes of several common products may cause tumors through a secondary mechanism, FDA concluded that "these foods and drugs are not, by reason of their capacity to induce liver damage when abused by being consumed at high levels, properly classified as carcinogenic because of their potential association with a higher rate of liver cancer."<sup>109</sup> In accordance with its practice of carefully evaluating the weight of the evidence suggesting a carcinogenic risk, FDA recently approved acesulfame potassium as a sugar substitute notwithstanding the development of tumors in animals tested at the highest doses.<sup>110</sup> In addition, although many traditional color additives contain known or suspected animal carcinogens, they have been sanctioned for use in food and other products without any label statements advising consumers of the animal test results.<sup>111</sup>

If a chronic health risk is not serious enough to justify a prohibition, FDA also will not mandate that a warning statement appear on the labels of food products. The Agency's hesitancy to demand precautionary labeling for either

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108. For example, when FDA approved a petition to allow selenium supplementation of livestock feed, it had to grapple with three animal studies that had found neoplastic lesions in the livers of rodents fed high doses of the substance. The Agency ultimately concluded that there was no cancer risk to humans from residues in animal tissue, discounting the observed tumors as linked to hepatotoxicity only at high doses. See 39 Fed. Reg. 1355 (1974); 38 Fed. Reg. 10,458 (1973).

109. 38 Fed. Reg. 10,458, 10,460 (1973); see also Richard A. Merrill et al., *The FDA's Authority Under the Delaney Clause to Consider Mechanisms of Action in Determining Whether Additives "Induce Cancer,"* 47 FOOD & DRUG L.J. 77 (1992). With improvements in scientific methods for detecting substances and evaluating their potential for causing cancer, such issues will arise even more frequently in the future. See 47 Fed. Reg. 14,464, 14,466 (1982) ("As the number of chemicals that are found to cause cancer in animals has grown, and as scientists' ability to detect the components of a substance has become more acute, the chances that a food additive or color additive will be found to be a carcinogenic chemical entity increases."); 44 Fed. Reg. 17,070, 17,075 (1979) (noting that detection limits have improved by several orders of magnitude).

110. See 21 C.F.R. § 172.800 (1993); 57 Fed. Reg. 6667, 6672-73 n.12 (1992). Aspartame, another sugar substitute, must only bear a cautionary statement alerting phenylketonurics, 21 C.F.R. § 172.804(e)(2) (1993), even though one of its metabolites is formaldehyde, an animal carcinogen. See 49 Fed. Reg. 6672, 6679-80 (1984); Council on Scientific Affairs, *Formaldehyde*, 261 JAMA 1183 (1989). FDA's decision not to require additional warnings for aspartame was upheld in *Community Nutrition Institute v. Young*, 773 F.2d 1356, 1366 (D.C. Cir. 1985).

111. For example, products containing FD&C Blue No. 2 need not provide any label warning despite evidence that prolonged exposure to this color additive resulted in a statistically significant increase in animal tumors. FDA explained that the available biological evidence discounting the risk of carcinogenicity outweighed the statistical evidence from the bioassays. 48 Fed. Reg. 5252, 5257-58 (1983), *aff'd*, 52 Fed. Reg. 8113 (1987), *aff'd*, *Simpson v. Young*, 854 F.2d 1429 (D.C. Cir. 1988). FDA also does not require cautionary labeling for products using any of many other color additives that contain known carcinogenic constituents or impurities because of the extremely low level of human risk they represent. See, e.g., 47 Fed. Reg. 49,628, 49,630 (1982) (D&C Green No. 5); 47 Fed. Reg. 14,138 (1982) (D&C Green No. 6); 48 Fed. Reg. 34,463, 34,464 (1983) (D&C Red No. 6 and D&C Red No. 7); 50 Fed. Reg. 35,774 (1985) (FD&C Yellow No. 5); 51 Fed. Reg. 41,765 (1986) (FD&C Yellow No. 6); 52 Fed. Reg. 19,719 (1987) (D&C Violet No. 2).

acute or chronic hazards associated with food, partly to avoid overwhelming consumers with inconsequential information, stands in marked contrast to its apparent readiness to demand warnings of all sorts of risks or related safety information in the labeling of cosmetics. As a whole, therefore, FDA's warning requirements applicable to food products are quite modest.

### C. *Nonprescription Drug Products*

As is the case with food products, FDA generally has not demanded the disclosure of chronic risk information in nonprescription drug labeling. With regard to acute risks, however, the Agency has demanded very detailed warning statements, with an emphasis on providing directions for safe use or highlighting the consequences of misuse. This emphasis contrasts with the vagueness of many of the Agency's cosmetic product warnings.

Label warnings on nonprescription drug products (often referred to as over-the-counter (OTC) drugs) generally are appropriate only for serious and substantiated human health risks. FDA has taken the position that "warning statements for OTC drug products should be limited to those that are scientifically documented, clinically significant, and important for the safe and effective use of the products by consumers."<sup>112</sup> The whole premise of making drugs available to consumers without a prescription is that self-diagnosis of certain conditions and self-treatment with these medications does not create safety concerns. Because few drugs are entirely risk free, OTC drug products can be marketed only if consumers are given information adequate to minimize the danger of any side effects.

Manufacturers of OTC drugs must abide by the terms of "monographs" issued as FDA regulations.<sup>113</sup> Monographs specify for particular categories of products, such as antacids or internal analgesics, the active ingredients and dosages that FDA has determined to be safe and effective. OTC drug monographs also specify acceptable labeling for these products. The Agency had originally mandated that manufacturers of OTC drug products use only the precise language relating to indications and directions for use set forth in the

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112. 53 Fed. Reg. 46,204, 46,213 (1988); *see also* 57 Fed. Reg. 58,356, 58,368 (1992) (stating warnings for OTC drug labeling should "include[] only essential information that is necessary to assure proper and safe use"); *id.* at 58,371 (Because "cardiovascular symptoms rarely occur with the use of OTC antihistamines . . . , the agency concludes that there is not an adequate basis for OTC antihistamine drug products to bear label warnings regarding possible adverse cardiovascular effects."); 40 Fed. Reg. 28,582, 28,583 (1975) (explaining that warning is justified only if "reasonable evidence exists indicating an association between a drug and a serious hazard"); 40 Fed. Reg. 8912 (1975) (stating warnings against misuse of aerosolized products only are necessary where misuse is "sufficiently frequent to constitute a hazard of widespread public concern").

113. 21 C.F.R. pt. 330 (1993). Deviations from the monographs would require premarket FDA approval. *Id.* § 330.11. (In some cases, such as the internal analgesic ibuprofen, monographs do not cover active ingredients because they have already received such separate approval.)

monographs.<sup>114</sup> Even when it revised its policy to allow for greater flexibility in labeling, FDA continued to demand verbatim adherence to any warnings prescribed in the regulations.<sup>115</sup> Manufacturers may include other cautionary information not mandated by FDA, but it must appear in some portion of the label other than the section containing the required warnings.<sup>116</sup> Some of the monographs also set forth “professional labeling” intended for physicians that often includes much more detailed precautionary information than is directed to consumers.<sup>117</sup>

Many of the OTC drug monographs require detailed warning statements in product labeling.<sup>118</sup> These specific warnings are in addition to the general warnings mandated for all nonprescription drug products, namely: “Keep this

114. 38 Fed. Reg. 31,260, 31,264 (1973). This rule, which became known as the “exclusivity” policy, was widely criticized. *See, e.g.,* Stephen McNamara, *FDA Regulation of Labeling and the Developing Law of Commercial Free Speech*, 37 FOOD DRUG COSM. L.J. 394, 400 (1982).

115. 21 C.F.R. § 330.1(c)(2)(vi) (1993); 51 Fed. Reg. 16,258, 16,260 (1986) (“The agency believes that concisely and consistently worded warnings are essential to the safe use of an OTC drug product and that permitting flexibility in this section of labeling could put consumers at risk.”). FDA recently gave manufacturers some limited flexibility in formulating OTC warning statements, authorizing the interchange of words such as “consult” and “ask,” and “physician” and “doctor.” 59 Fed. Reg. 3998, 4000 (1994) (to be codified at 21 C.F.R. § 330.1(i)).

116. *See* 56 Fed. Reg. 63,554, 63,566 (1991) (discussing warning that cautioned against using OTC dandruff products with children younger than two years, a warning recommended by expert panel but rejected as unnecessary by FDA); 50 Fed. Reg. 2124, 2128 (1985) (even truthful and nonmisleading information “may not appear in any portion of the labeling required by the monograph and may not detract from such required information”).

117. *See, e.g.,* 53 Fed. Reg. 46,204, 46,258-59 (1988) (to be codified at 21 C.F.R. § 343.80) (proposed Nov. 16, 1988) (setting forth professional labeling for internal analgesics, with sections entitled “Precautions” and “Adverse Reactions,” and including all of the monograph warnings under latter heading along with information about other side effects of aspirin use including gastrointestinal bleeding). FDA also has proposed mandating a cautionary statement directed to consumers regarding certain professional uses. 58 Fed. Reg. 54,224, 54,226 (1993) (to be codified at 21 C.F.R. § 201.314(i)(1)) (proposed Oct. 20, 1993) (“IMPORTANT: See your doctor before taking this product for your heart or for other new uses of aspirin because serious side effects could occur with self treatment.”).

118. For example, OTC nighttime sleep-aid drug products must include the following statements in the “Warnings” section of the label:

- (1) “Do not give to children under 12 years of age.”
- (2) “If sleeplessness persists continuously for more than 2 weeks, consult your doctor. Insomnia may be a symptom of serious underlying medical illness.”
- (3) “Do not take this product if you have asthma, glaucoma, emphysema, chronic pulmonary disease, shortness of breath, difficulty in breathing, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.”
- (4) “Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor.”

21 C.F.R. § 338.50(c) (1993). Standardized warnings also have been established in final monographs for several other products including: antacids, *id.*, § 331.30(c); first aid antibiotic products, *id.*, § 333.150(c); antiemetic drugs, *id.*, § 336.50(c); stimulants, *id.*, § 340.50(c); antihistamines, *id.*, § 341.72(c); antitussives, *id.*, § 341.74(c); bronchodilators, *id.*, § 341.76(c); expectorants, *id.*, § 341.78(c); topical otic drugs, *id.*, § 344.50(c); and hemorrhoidal products, *id.*, § 346.50(c). FDA regulations also contain a variety of other recommended warnings for various OTC drugs not governed by monographs. *See id.* pt. 369.

and all drugs out of the reach of children," and "In case of accidental overdose [or "ingestion"], seek professional assistance or contact a poison control center immediately."<sup>119</sup> These "Warnings" are action-oriented directives intended to ensure safe product use rather than mere disclosures of risk information.<sup>120</sup>

Another general warning required for OTC drug products intended for systemic absorption cautions pregnant and nursing women to "seek the advice of a health professional before using this product."<sup>121</sup> In addition to the written warning, a symbol that conveys the intent of the warning may be used "to attract the attention of women who do not read English."<sup>122</sup> FDA rejected requests for flexibility in phrasing the required statement, however, explaining that a standardized warning "would insure that the intended message is conveyed uniformly to all women and would prevent consumer confusion."<sup>123</sup> (The Agency also discounted a concern that the general warning for OTC products, coupled with BATF's contemporaneous decision not to require a

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119. *Id.* § 330.1(g). One court has held that the adequacy of a warning on an OTC topical analgesic product was for a jury to decide in light of expert testimony that the FDA warning to keep medications out of children's reach "was very general and that its effect is 'watered down' by the fact that the same warning appears on numerous products that are not harmful (i.e., Flintstone Vitamins and Hydrocortisone Cream)." *Hahn v. Sterling Drug, Inc.*, 805 F.2d 1480, 1482 (11th Cir. 1986). The direction to "keep out of the reach of children" must appear in the labeling of a number of hazardous products not regulated by FDA. *See* 15 U.S.C. § 1261(p)(1)(i) (1988) (FHSA); 16 C.F.R. § 1500.3(a)(14)(i)(J)(1) (1993) (CPSC rule for hazardous substances); 40 C.F.R. § 156.10(h)(1)(i) (1993) (EPA requirement for pesticides).

120. Indeed, FDA sometimes struggles when deciding whether information should appear in the "Warnings" or "Directions for Use" section of labeling. *See, e.g.*, 58 Fed. Reg. 54,224, 54,226 (1993) (to be codified at 21 C.F.R. § 201.314(i)(1)) (proposed Oct. 20, 1993) (statement on professional uses of aspirin); 58 Fed. Reg. 45,194, 45,198 (1993) ("[C]ritical information alerting the consumer about the possible consequences of not taking these products correctly should be appropriately placed in both the 'Warnings' and the 'Directions' sections of the products' labeling."); 58 Fed. Reg. 28,194, 28,241 (1993) (to be codified at 21 C.F.R. pt. 352) (proposed May 12, 1993) (in tentative final monograph for sunscreen products, FDA decided to move age limitation information from "Warnings" to "Directions" section); *cf. id.* at 28,236 (proposing to require a "SUN ALERT" statement which "combines the attributes of an indication and a warning" and, therefore, "should stand on its own and be distinctive in labeling").

121. 21 C.F.R. § 201.63(a) (1993).

122. 47 Fed. Reg. 54,750, 54,753 (1982); *see also* 59 Fed. Reg. 1638, 1639 (1994) (to be codified at 21 C.F.R. § 109.16(b)(1)(i)) (permitting use of symbol to indicate lead ceramicware is not intended for food use). Infant formulas must use pictograms to accompany directions for use. 21 C.F.R. § 107.20(b) (1993). This is mandatory because of the importance that directions for such products be "understandable to all users, including those who have difficulty reading English or perhaps any language." 48 Fed. Reg. 31,880, 31,883 (1983); *see also* 50 Fed. Reg. 1833, 1836-37 (1985). FDA has not required bilingual labeling on OTC or other products, but, subject to certain limitations, manufacturers are permitted to provide label information in another language. *See* 21 C.F.R. §§ 101.15(c) (food), 201.15(c) (drugs), 701.2(b) (cosmetics), 801.15(c) (medical devices) (1993); *see also* 58 Fed. Reg. 44,081 (1993) (to be codified at 21 C.F.R. § 101.9(d)(14)) (permitting dual language labeling in nutrition information panel required for food products); 53 Fed. Reg. 21,633, 21,636 (1988) ("FDA encourages the preparation of labeling to meet the needs of non-English speaking or special user populations so long as such labeling fully complies with agency regulations."); 48 Fed. Reg. 31,880, 31,883 (1983) (recognizing difficulties likely to arise with multilingual labeling, including "illiteracy in other label languages and space limitations").

123. 47 Fed. Reg. 54,750, 54,753 (1982). In pursuit of assuring such uniformity, FDA explained that its regulation would preempt state requirements. "A single national warning will help ensure that consumers receive clear, unambiguous, and consistent information on the labeling of OTC drugs concerning use by pregnant or nursing women. Differing State requirements could conflict with the Federal warning, cause confusion to consumers, and otherwise weaken the Federal warning." *Id.* at 54,756.

similar warning on the labels of alcoholic beverages, might create the impression that pregnant and nursing women could safely use alcohol.<sup>124</sup>) More recently, FDA required that OTC drug products containing aspirin include the following statement immediately after the general pregnancy warning:

“IT IS ESPECIALLY IMPORTANT NOT TO USE” (select “ASPIRIN” or “CARBASPIRIN CALCIUM,” as appropriate)  
“DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY DIRECTED TO DO SO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY.”<sup>125</sup>

FDA rejected comments asserting that this warning was unnecessary in light of the general warning against using any OTC drug product during pregnancy without a physician’s guidance.<sup>126</sup>

Nonprescription drug products containing aspirin also must include a warning statement concerning a serious risk to children.

WARNING: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye syndrome, a rare but serious illness reported to be associated with aspirin.<sup>127</sup>

When the risk of Reye syndrome first came to light in the early 1980s, FDA responded with a public education campaign that included newspaper columns, radio public service announcements, and print advertisements.<sup>128</sup> Shortly thereafter, although it lauded the industry’s “unprecedented voluntary program” of cautionary labeling and advertising, FDA proposed a mandatory label

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124. *Id.* at 54,754 (noting its lack of jurisdiction over alcoholic beverages and disputing suggestion that inconsistent labeling for these dissimilar products might imply alcohol is safe). By comparison, FDA justified an additional third-trimester pregnancy warning for aspirin products in part because OTC analgesics containing ibuprofen already carry such a warning and an inconsistency might lead consumers mistakenly to believe that aspirin is safer in this respect. 55 Fed. Reg. 27,776, 27,782 (1990) (“[H]aving different warnings on OTC drug products containing these ingredients could cause consumers to perceive that there is a difference in the safety of using these ingredients during the third trimester of pregnancy when, in fact, there is no established significant safety difference.”).

125. 21 C.F.R. § 201.63(e) (1993). The Agency’s choice of placement (immediately after the general pregnancy warning) and type style sought to ensure maximum prominence for the new warning. 55 Fed. Reg. 27,776, 27,782-83 (1990).

126. *Id.* at 27,778, 27,782-83.

127. 21 C.F.R. § 201.314(h)(1) (1993). To ensure prominence, this statement must appear before any other warning on the label. *Id.* § 201.314(h)(2). FDA rejected a suggestion, however, that a boxed warning was necessary to highlight the statement. 51 Fed. Reg. 8180, 8181 (1986). The tentative final monograph for internal analgesic products also includes a number of other warnings applicable to aspirin. See 53 Fed. Reg. 46,204, 46,256 (1988) (to be codified at 21 C.F.R. § 343.50(c)) (proposed Nov. 16, 1988).

128. 50 Fed. Reg. 51,400, 51,401 (1985). The campaign continued even after the warning became mandatory. 53 Fed. Reg. 21,633 (1988).

warning because of its concerns that the "multiplicity of warning statements . . . may cause consumer confusion."<sup>129</sup> Reiterating its "well-established policy of promoting uniformity in the area of labeling,"<sup>130</sup> the Agency imposed a mandatory warning requirement which would expire after two years.<sup>131</sup> A slightly revised warning was made a permanent requirement in 1988, after FDA rejected suggestions urging "more drastic measures [such as] banning use of aspirin in products for individuals under 21 years of age or limiting such products to prescription use."<sup>132</sup>

As illustrated above, FDA has required numerous and detailed precautionary statements about acute nonprescription drug risks.<sup>133</sup> By contrast, chronic risk statements are rare. Indeed, one recent proposal to require a warning of chronic hazards in the labeling of OTC drug products has engendered substantial controversy. In 1991, the Agency suggested that it may be appropriate for nonprescription drugs containing doxylamine succinate, at that time an antihistamine ingredient tentatively approved by FDA,<sup>134</sup> to carry a carcinogenicity warning in their labeling. An FDA official offered the following idea:

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129. 50 Fed. Reg. 51,400, 51,402 (1985).

130. *Id.* at 51,403.

131. 51 Fed. Reg. 8180, 8182 (1986). For a more detailed account of the history behind the early Reye syndrome warning efforts, see *American Home Products Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 137-41 (S.D.N.Y. 1987).

132. 53 Fed. Reg. 21,633, 21,635 (1988); *see also* 58 Fed. Reg. 54,228 (1993) (proposing revision in language of warning and also extending it to non-aspirin salicylates); 58 Fed. Reg. 26,886, 26,886-87 (1993) (proposing same Reye syndrome warning for OTC products containing bismuth subsalicylate).

133. In addition, a few nonprescription medical devices are subject to detailed FDA warning requirements. For example, every tampon package must at a minimum include the following statement: "ATTENTION: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information." 21 C.F.R. § 801.430(c) (1993). The accompanying package insert must include a number of detailed statements describing the precise risks of TSS and instructions for minimizing the risk. *Id.* § 801.430(d). Because the epidemiological data indicated a risk of approximately one case of TSS for every 10,000 tampon users annually, 47 Fed. Reg. 26,982 (1982), one manufacturer argued that the proposed labeling requirements were unjustified in light of the Agency's failure to require warnings for other products allegedly posing higher lifetime cancer risks. *Id.* at 26,985. FDA responded by explaining that the epidemiological studies linking TSS to tampon use provided a much firmer risk estimate than extrapolations from animal bioassays of the other substances, and that the risk of TSS would be significantly greater if expressed as a lifetime rather than annual risk. *Id.*; *cf.* 44 Fed. Reg. 59,509, 59,512 (1979) (in responding to similar arguments against the 4-MMPD warning, FDA stated that "a government agency is not estopped from taking warranted action against a particular hazard because of the existence of other hazards on which it has not taken action"). Specific warning requirements also have been established for denture repair kits, 21 C.F.R. § 801.405(b)(3) (1993), hearing aids, *id.* § 801.420(c)(2), and intrauterine contraceptive devices (IUDs), *id.* § 801.427(b).

134. 52 Fed. Reg. 31,892, 31,913 (1987) (to be codified at 21 C.F.R. § 341.12(g)) (proposed Aug. 24, 1987). When FDA originally published its final monograph on OTC antihistamine products, it deferred making a final decision on doxylamine. 57 Fed. Reg. 58,356, 58,357 (1992).



WARNING: Use of this product may be hazardous to your health. This product contains doxylamine succinate which has been determined to produce tumors in laboratory animals.<sup>135</sup>

Noting that the language was “similar to the required warning for products containing saccharin,” the official asserted that “the format should already be familiar to many consumers.”<sup>136</sup>

The Agency’s suggested warning for doxylamine would have been unprecedented. Indeed, FDA previously had noted the incongruity of providing such warnings on products intended for lay use:

Suitable labeling of an OTC drug may provide sufficient safeguards for a drug that presents such indirect risks [as drowsiness]. When a drug presents serious direct risks (e.g., of cancer or other serious disease), adequate labeling for any lay use without medical supervision generally cannot be written.<sup>137</sup>

The Agency has not required that other OTC drug products carry warnings of unsubstantiated chronic risks.<sup>138</sup> In conjunction with its proposal to prohibit the use of saccharin in foods, FDA had proposed a similar warning for the artificial sweetener if sold as an OTC drug; the idea was dropped, however, after Congress established its moratorium and disclosure statement (but not a “Warning”) for food products containing saccharin.<sup>139</sup> Although FDA eventually

135. Letter from William E. Gilbertson, Director of FDA’s Division of OTC Drug Evaluation, to R. William Soller, Senior Vice President and Director of Science and Technology, Nonprescription Drug Manufacturers Association (July 18, 1991) (on file with the author).

136. *Id.* An FDA advisory committee had reviewed the results of rodent bioassays which found some increase in benign liver and thyroid tumors after high-dose, lifetime exposures, but it concluded that a human cancer risk was not likely and made no recommendation to restrict the use of doxylamine. Transcript of meeting of FDA’s Pulmonary-Allergy Drugs Advisory Committee, at 172-74 (June 14, 1991) (on file with the author). At the same time, however, the committee suggested that the animal data not be withheld from the public. *Id.* at 175-82. FDA interpreted this suggestion as a recommendation to include a warning statement in the labeling of the product.

137. 44 Fed. Reg. 51,512, 51,525 (1979). The very attempt to formulate an accurate label statement for doxylamine underscores the primary point that there was nothing to disclose. For example, it would make no sense to advise consumers that “doxylaminesuccinate has been associated with the development of benign tumors in certain rodents, but an FDA advisory committee has concluded that this ingredient is not likely to pose any human health risk whatsoever.” *Cf.* Cooper, *supra* note 105, at 620-21 (listing examples of nonsensical warnings).

138. For instance, FDA allows the use of coal tar as an active ingredient for the treatment of psoriasis and other less serious scalp conditions, 21 C.F.R. § 358.710 (1993), even though the Agency conceded that “it is well-established that coal tar contains substances that possess carcinogenic properties.” 51 Fed. Reg. 27,346, 27,348 (1986). Coal tar products need not carry any mention of animal toxicity data on their labels. *Id.* at 27,349 (after discussing reassuring clinical experience with coal tar drugs, FDA decided some guidance against prolonged use would be justified but did not deem it necessary to warn consumers of “relatively small” cancer risk); *see also* 56 Fed. Reg. 63,554, 63,565 (1991). Required warnings appear in 21 C.F.R. § 358.750(c) (1993).

139. *See supra* notes 26-29 and accompanying text.

relented and dropped the proposed warning for doxylamine,<sup>140</sup> the Agency still is actively considering chronic risk labeling for benzoyl peroxide, a widely used topical acne ingredient.<sup>141</sup>

Consistent with its treatment of food and most cosmetic products, FDA generally has not required that OTC labeling discuss low-level, chronic health hazards.<sup>142</sup> In contrast to its treatment of food products, however, the Agency's practice with respect to OTC drugs involves the imposition of detailed and quite rigid warning requirements for acute hazards. For the most part, FDA has required instructional warnings that more closely resemble directions for use than descriptions of the risks posed by use or misuse. When specific health hazards are identified in a required cautionary statement, as in the case of the third-trimester pregnancy warning for products containing aspirin, it is done primarily to underscore the importance of abiding by the directives contained in the warning. Because OTC products are intended for self-treatment, the emphasis on instructional warnings rather than risk disclosures seems entirely appropriate.

#### D. *Prescription Drugs*

Medications that cannot be used safely by consumers without the diagnosis and supervision of a physician are designated as prescription drugs and can be dispensed only on the order of a licensed medical practitioner, making such medications unlike most other consumer products. As one would expect, physician labeling contains far more detailed risk information than is generally possible to provide in the labeling of most consumer products, and physician labeling includes information about both acute and chronic risks. Nonetheless, FDA's elaborate labeling requirements for prescription drugs provide instructive

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140. 59 Fed. Reg. 4216, 4217 (1994) (deciding instead to publish informative article in FDA CONSUMER magazine).

141. FDA deferred final action on benzoyl peroxide when it issued the monograph for topical acne products. 56 Fed. Reg. 41,008, 41,009 (1991) (animal studies suggested that ingredient may promote tumors). Benzoyl peroxide may continue to be marketed while carcinogenicity studies are underway, but, as with doxylamine, FDA is considering a labeling disclaimer requirement in the meantime. See F-D-C REPORTS ("The Tan Sheet"), Nov. 29, 1993, at 8, 9; F-D-C REPORTS ("The Rose Sheet"), Jan. 17, 1994, at 8. By contrast, FDA has not suggested any need for cautionary labeling pending its decision on fears that the weight control ingredient phenylpropanolamine may cause hemorrhagic stroke. See F-D-C REPORTS ("The Pink Sheet"), Feb. 15, 1993, at T&G-1.

142. Like foods, the labeling of nonprescription drugs must disclose the presence of Yellow No. 5, 21 C.F.R. § 201.20(a) (1993), and alert phenylketonurics if the product contains aspartame. *Id.* § 201.21(b). FDA has proposed to require a declaration of the sodium content of OTC drugs. 56 Fed. Reg. 19,222 (1991) (to be codified at 21 C.F.R. pts. 201, 331) (proposed April 25, 1991). Unlike rule applicable to food products, however, the warning would be required above a certain threshold. *Id.* at 19,226 (to be codified at 21 C.F.R. § 201.64(c)) (if maximum daily dose of OTC drug contains more than 140 mg of sodium, its label must warn: "Do not use this product if you are on a sodium restricted diet unless directed by a doctor.").

contrasts, particularly when compared with OTC drug warnings directed to lay consumers.

Prescription drugs are potent medications that unavoidably are associated with adverse effects,<sup>143</sup> but the benefits of using such drugs outweigh the accompanying risks so long as the expert judgment of a trained professional is first applied in the decision to use a drug for a particular patient. The best mechanism for achieving these ends is detailed labeling that includes all pertinent risk information. The labeling for prescription drugs provides comprehensive information to help physicians in making therapeutic risk-benefit decisions in individual cases. Consequently, when FDA reviews new drug applications, it carefully considers all aspects of proposed labeling.<sup>144</sup> In promulgating its regulation governing the content and format of "package inserts," FDA emphasized that "the decision as to whether a warning is legally required for the labeling of a drug must rest with the agency."<sup>145</sup>

In the labeling for any prescription drug, FDA demands that cautionary information be categorized according to the relative severity of the hazard and the degree to which the risk has been substantiated. Package inserts contain many detailed paragraphs of information about indications for use and side effects to assist physicians in making prescribing decisions. Topic headings in prescription drug labeling should include: Clinical Pharmacology, Indications and Usage, Contraindications, Warnings, Precautions, and Adverse Reactions.<sup>146</sup> The placement of risk information into one of the latter several categories depends on the relative severity of the hazard, ranging from situations where risks "clearly outweigh any possible benefit" (to be noted as contraindications)<sup>147</sup> to non-serious side effects that occur with a frequency of less than one

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143. It is well known, for instance, that certain patients are allergic to penicillin, and approximately 300 persons (representing 0.001% of all treated patients) die each year from anaphylactic reactions. ALFRED G. GILMAN et al., *GOODMAN AND GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS* 1083 (8th ed. 1990). All told, adverse drug reactions may account for many thousands of fatalities in the United States each year. See John A. Anderson, *Allergic Reactions to Drugs and Biological Agents*, 268 JAMA 2845 (1992); Strom, *Pharmacoepidemiology: Current Status, Prospects, and Problems*, 113 ANNALS INTERNAL MED. 179 (1990).

144. See Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 11 (1973) ("The agency approves, and for practical purposes prescribes, the labeling that the drug must bear."). Proposed labeling must be included in the application, and the agency may condition final approval on revisions. 21 U.S.C. § 355(b)(1)(F) (1988); 21 C.F.R. §§ 314.50(c)(2)(i), 314.110 (1993). Although decisions are made for each new drug independently at the time of their approval, the agency does attempt to achieve consistency in the labeling required for similar prescription drugs. See, e.g., 21 C.F.R. § 310.500(e) (1993) (specifying appropriate labeling for digoxin); 22 FDA MEDICAL BULL. 2 (1992) (describing class-wide labeling changes, including a boxed warning against use during pregnancy, for one type of antihypertensive drug); 49 Fed. Reg. 14,303 (1984) (announcing class labeling guideline for oral hypoglycemic drugs and issuing a mandatory warning requirement); 45 Fed. Reg. 76,356 (1980) (announcing class labeling guideline for single-entity barbiturates).

145. 44 Fed. Reg. 37,434, 37,453 (1979).

146. 21 C.F.R. § 201.56 (1993).

147. *Id.* § 201.57(d); see also *McFadden v. Haritatos*, 448 N.Y.S.2d 79, 81 (N.Y. App. Div. 1982) ("[T]he caveats against use beginning with 'CONTRAINDICATIONS' were and are set forth in the regulations in a descending order of importance. Thus, as known adverse side effects increase in intensity and severity, the manufacturer's warning in respect to the drug's potential for harm should accordingly

in a thousand (to be noted as "rare" adverse reactions).<sup>148</sup> This hierarchy stands in marked contrast to the Agency's largely undifferentiated approach for OTC drug labeling.<sup>149</sup>

The Warnings section of the package insert is reserved for risks that are more serious than adverse reactions but are not so serious as to clearly outweigh possible benefits of a drug. Particularly serious risks may have to be highlighted as a "boxed warning."<sup>150</sup> For example, the package insert for the antiepileptic drug Depakene (valproic acid) carries a boxed warning which provides in part that:

HEPATIC FAILURE RESULTING IN FATALITIES HAS OCCURRED IN PATIENTS RECEIVING VALPROIC ACID. . . . SERIOUS OR FATAL HEPATOTOXICITY MAY BE PRECEDED BY NON-SPECIFIC SYMPTOMS SUCH AS LOSS OF SEIZURE CONTROL, MALAISE, WEAKNESS, LETHARGY, FACIAL EDEMA, ANOREXIA, AND VOMITING. PATIENTS SHOULD BE MONITORED CLOSELY FOR APPEARANCE OF THESE SYMPTOMS.<sup>151</sup>

The Agency has emphasized that, "to ensure the significance of boxed warnings in drug labeling, they are permitted in labeling only when specifically required by FDA."<sup>152</sup>

In certain cases, information concerning uncommon but potentially serious allergic reactions may have to appear in the Warnings section. For example,

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ascend to a higher category.").

148. 21 C.F.R. § 201.57(g)(2) (1993).

149. See 57 Fed. Reg. 58,356, 58,368 (1992) ("[T]he agency does not believe that the importance of the 'Warnings' section will be undermined if all of the information about unsafe use, side effects, and adverse reactions is presented under a single heading."). By contrast, when professional labeling is set forth in the monograph, most of the "Warnings" appearing in consumer labeling generally are listed as "Adverse Reactions." See *supra* note 117.

150. 21 C.F.R. § 201.57(e) (1993). For example, FDA has mandated the use of boxed warnings against the use of thyroid and digitalis preparations in the treatment of obesity. *Id.* §§ 201.316, 201.317.

151. 47 PHYSICIANS DESK REFERENCE 512 (1993). The PHYSICIANS DESK REFERENCE (PDR) is an annual compilation of prescription drug package inserts provided to practicing physicians at no charge. Because physicians normally do not dispense drugs directly to patients, they do not see the labeling included with the product and must instead rely on copies received from sales representatives or compilations such as the PDR. Such additional labeling must contain the same information as the approved package insert, 21 C.F.R. §§ 201.100(d)(2), 202.1(l)(2) (1993), and manufacturers have been held liable for failure to warn when the PDR does not contain the same warnings. *E.g.*, *Baker v. St. Agnes Hospital*, 421 N.Y.S.2d 81, 86 (N.Y. App. Div. 1979).

152. 44 Fed. Reg. 37,434, 37,448 (1979). Thus, because it was unpersuaded by the data, FDA rejected a petition requesting that the labeling of oral contraceptives include a boxed warning concerning the risk of breast cancer. F-D-C REPORTS ("The Pink Sheet"), May 31, 1993, at T&G-18; *cf.* F-D-C REPORTS ("The Pink Sheet"), May 24, 1993, at T&G-3 (describing FDA request that all manufacturers of contrast agents include boxed warning against intrathecal use). FDA prohibits certain types of advertising for prescription products that carry a boxed warning. 21 C.F.R. § 202.1(e)(2)(i) (1993).

prescription drugs made with sulfiting agents must include a lengthy warning.<sup>153</sup> A similar statement concerning possible allergic reactions to Yellow No. 5 is required, but only in the Precautions section of prescription drug labeling.<sup>154</sup> Such detailed precautionary information contrasts with the simple ingredient declarations FDA requires when these additives are present in food and nonprescription drug products.<sup>155</sup>

Whichever category is appropriate for the disclosure of hazard information in the package insert, FDA demands that the risk be substantiated. The regulations provide, for instance, that only “[k]nown hazards and not theoretical possibilities shall be listed” as contraindications.<sup>156</sup> The Agency explained in the preamble to this rule that “including theoretical hazards as contraindications in drug labeling would cause that very important section of the labeling to lose its significance.”<sup>157</sup> A statement in the Warnings section is only appropriate after “reasonable evidence of an association of a serious hazard with a drug” is found, though “a causal relationship need not have been proved.”<sup>158</sup> Evidence from long-term animal studies normally should be included in the Precautions section, together with an explanation of species and bioassay results,<sup>159</sup> though in some cases “serious animal toxicity data may require warnings in drug labeling.”<sup>160</sup> FDA even requires that the Adverse Reactions section, which contains some of the least serious risk information in the package insert, only include the side effects that are “reasonably associated” with use of the drug.<sup>161</sup> Although all “adverse experiences” with a new drug must be reported to the

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153. The Warnings section would have to include the following statement:

Contains (*insert the name of the sulfite, e.g., sodium metabisulfite*), a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

21 C.F.R. § 201.22(b) (1993).

154. *Id.* § 201.20(b), discussed in *supra* note 96. In addition, the statement alerting phenylketonurics that products sweetened with aspartame contain phenylalanine must appear in the “Precautions” section of the package insert. *Id.* § 201.21(c).

155. *See supra* notes 91-92.

156. 21 C.F.R. § 201.57(d) (1993).

157. 44 Fed. Reg. 37,434, 37,447 (1979).

158. 21 C.F.R. § 201.57(e) (1993); *see also* 40 Fed. Reg. 28,582, 28,583 (1975).

159. 21 C.F.R. § 201.57(f)(5) (1993). FDA explained that: “This information may be of value to physicians in deciding whether to prescribe a particular drug for an indication, when animal data demonstrate a relationship between the use of the drug and carcinogenesis, mutagenesis, or impairment of fertility and no comparable human data exist, and when equally effective alternative drugs that do not present a risk are available.” 44 Fed. Reg. 37,434, 37,450 (1979).

160. *Id.* at 37,448; *see* 21 C.F.R. § 201.57(e) (1993).

161. 21 C.F.R. § 201.57(g) (1993). FDA recently asked manufacturers of fertility drugs to revise the Adverse Reaction section of labeling to disclose recent information about the possible risk of ovarian cancer. *See* FDA Talk Paper No. T93-3 (Jan. 13, 1993) (six cases had been reported to FDA, and one published study suggested causal association, but Agency explained that “this labeling change is being made only in one section of the label without a conclusion about causality”).

Agency, whether or not reasonably associated with use of the drug,<sup>162</sup> for purposes of labeling an adverse reaction "would not include unsubstantiated reactions."<sup>163</sup> When substantiated health hazards are discovered, however, manufacturers have a duty to alert the Agency and to add new risk information to labeling.<sup>164</sup>

FDA's rules governing the disclosure of potential risks of use by pregnant women illustrate the interplay between categorization and substantiation. A "Pregnancy category" designation, accompanied by a specified explanation and any additional information concerning the risk of birth defects, must appear in the Precautions section of most package inserts. The particular designation depends on the available evidence of a drug's potential teratogenicity. If adequate and well-controlled clinical studies have failed to demonstrate any risk to the fetus, the drug is to be designated as Pregnancy category A.<sup>165</sup> Pregnancy category B is appropriate in cases where clinical studies have not been performed in pregnant women, but the data from animal testing fail to demonstrate a risk to the fetus. Pregnancy category C should be used if the animal test results were unfavorable but the benefits of use outweigh the possible risk of birth defects.<sup>166</sup> In the event that there is positive human evidence of a risk to the fetus, but the potential benefits from use of the drug by pregnant women may be acceptable, Pregnancy category D should appear in the Precautions section of the package insert along with a cross-reference to the Warnings section which must include a specified hazard statement.<sup>167</sup> Finally, if evidence from use in humans or animals discloses a risk of birth defects that clearly outweighs any possible benefit of using the drug during pregnancy, Pregnancy category X is appropriate, along with a cross-reference to the Contraindications section.<sup>168</sup> Although the use of different letters for each category is unique, the scheme used for teratogenic risk information reflects

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162. See 21 C.F.R. §§ 310.305(b), 314.80(a) (1993); 50 Fed. Reg. 7452, 7471 (1985).

163. 44 Fed. Reg. 37,434, 37,453 (1979) ("adverse experiences are not synonymous with adverse reactions and should not be included in prescription drug labeling"); see also Thomas Scarlett, *The Relationship Among Adverse Drug Reaction Reporting, Drug Labeling, Product Liability, and Federal Preemption*, 46 FOOD DRUG COSM. L.J. 31, 36 (1991) ("[A]lthough the FDA prefers that companies err on the side of caution and report more rather than less, the agency does not want to process a lot of pointless ADR information or have labeling cluttered up with speculative warnings."). FDA's distinction between adverse experiences for purposes of spontaneous reporting and adverse reactions for purposes of labeling differs from the systems used in European and other countries. Garth K. Graham, *Can Safety Labeling Be Harmonized?*, 27 DRUG INFO. J. 447, 448 (1993).

164. 44 Fed. Reg. 37,434, 37,447 (1979) ("[T]he act and FDA regulations require a warning in drug labeling as soon as a hazard is associated with the use of a drug."). The extent of manufacturers' ability to revise approved labeling to incorporate new risk information has been an issue of considerable controversy in products liability litigation involving prescription drugs. See *infra* notes 333-341 and accompanying text.

165. 21 C.F.R. § 201.57(f)(6)(i)(a) (1993).

166. *Id.* § 201.57(f)(6)(i)(b)&(c).

167. *Id.* § 201.57(f)(6)(i)(d).

168. *Id.* § 201.57(f)(6)(i)(e). The Agency explained that the use of these pregnancy categories is "necessary to provide consistency in prescription drug labeling." 44 Fed. Reg. 37,434, 37,451 (1979).

FDA's general categorization and substantiation requirements applicable to other prescription drug hazards.

Prescription drug warning requirements have not been confined to product labels for physicians. On several occasions over the last two decades, FDA has proposed requiring that drug information be given directly to patients. In 1970, for example, the Agency issued a requirement for a "patient package insert" (PPI) for oral contraceptives.<sup>169</sup> The insert included the following cautionary information:

Do Not Take This Drug Without Your Doctor's Continued Supervision. The oral contraceptives are powerful and effective drugs which can cause side effects in some users and should not be used at all by some women. The most serious known side effect is abnormal blood clotting which can be fatal.<sup>170</sup>

In imposing this requirement, FDA explained that oral contraceptives, which pose low-probability but potentially serious risks, were taken by healthy women as a matter of choice over a long period of time, and that "many patients [were] not receiving the needed information in an organized, comprehensive, understandable and handy-for-future reference form."<sup>171</sup> Several years later, the Agency promulgated a regulation requiring a similar PPI for drug products containing estrogens,<sup>172</sup> though in this case the primary goal was to dissuade inappropriate use.<sup>173</sup>

In 1979, based on studies indicating the usefulness of supplying written information directly to patients, FDA proposed regulations that would have

169. 35 Fed. Reg. 5962 (1970); 35 Fed. Reg. 9001 (1970).

170. 21 C.F.R. § 130.45(d)(1) (1970). The requirement has been revised several times since then, and includes far more detailed warnings and information about side effects. 21 C.F.R. § 310.501 (1993); FDA, *Patient Package Insert Text for Estrogen-Progestogen Oral Contraceptives*, Docket No. 86D-0335 (Feb. 1987) (on file with the author). This PPI was held to provide an adequate warning in a recent products liability case, *MacPherson v. Searle & Co.*, 775 F. Supp. 417, 425 (D.D.C. 1991), and FDA is now considering further revisions to improve clarity of the PPI, such as adding a single cover page that highlights the information found in the full insert. See F-D-C REPORTS ("The Pink Sheet"), Nov. 1, 1993, at T&G-1. A similar PPI requirement exists for IUDs. 21 C.F.R. §§ 310.502, 801.427(b)(2) (1993).

171. 35 Fed. Reg. 9001, 9002 (1970). As explained by a former Chief Counsel of FDA: "Labeling is usually the appropriate regulatory strategy for those relatively few circumstances where a large proportion of consumers will take the trouble to assess benefits and risks before deciding whether to use a particular product, and where useful information on risks can in fact be provided. The best example is contraceptive drugs and devices." Richard M. Cooper, *A Time to Warn and A Time to Ban*, in *PRODUCT LABELING AND HEALTH RISKS*: BANBURY REPORT 6, at 299 (Louis A. Morris et al. eds., 1980). See generally Marsha W. Gardner, *Increasing Patient Awareness in Drug Therapy: Ramifications of a Patient Package Insert Requirement*, 66 GEO. L.J. 837 (1978); Richard A. Guarino, *Patient Package Inserts*, 34 FOOD DRUG COSM. L.J. 116 (1979).

172. 42 Fed. Reg. 37,636 (1977), 21 C.F.R. § 310.515 (1993); see also *Pharmaceutical Mfrs. Ass'n v. FDA*, 484 F. Supp. 1179 (D. Del.) (rejecting challenge to this regulation), *aff'd*, 634 F.2d 106, 108 (3d Cir. 1980) (per curiam).

173. See 9 FDA DRUG BULL. 2, 3 (1979).

required PPIs for most prescription drug products.<sup>174</sup> Although the Agency recognized that consumers may have difficulties understanding some of the concepts and information described in professional labeling,<sup>175</sup> the proposed PPIs would have differentiated between Contraindications, Warnings, Precautions, and Adverse Reactions in much the same way as package inserts directed to physicians do.<sup>176</sup> The proposal was never implemented,<sup>177</sup> but pharmaceutical companies sometimes voluntarily provide separate information for patients, and FDA recently expressed renewed interest in requiring the distribution of prescription drug information directly to patients.<sup>178</sup> For the most part, however, prescription drug labeling remains geared toward providing physicians with the information that may be relevant in deciding whether to prescribe a medication for a particular patient.<sup>179</sup> Although the level of detail generally could not be replicated in the labeling of other products, FDA requirements that risk information be substantiated and categorized should be relevant no matter what the type of product or the relative sophistication of the audience.

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174. 44 Fed. Reg. 40,016, 40,020-21 (1979).

175. *Id.* at 40,026.

176. *Id.* at 40,029. Indeed, information about potential carcinogenicity and mutagenicity based on animal or laboratory testing would appear in the Precautions section of the PPI along with other items such as information concerning possible drug interactions. *Id.*

177. After receiving various complaints about the costs of such an undertaking, FDA instead established a three-year pilot program mandating the distribution of PPIs for 10 classes of drugs. 45 Fed. Reg. 60,754, 60,773 (1980) (anticipating that PPIs for these drugs would "help prevent serious side effects"). Even this scaled-down program was stayed by the Agency in 1981. 46 Fed. Reg. 23,739, 23,815 (1981). It was revoked the following year. 47 Fed. Reg. 39,147 (1982); see also Rosalind M. Kendellen, *The Food and Drug Administration Retreats from Patient Package Inserts for Prescription Drugs*, 40 FOOD DRUG COSM. L.J. 172 (1985).

178. 59 Fed. Reg. 20,356 (1994).

179. The labeling of prescription or otherwise restricted medical devices must bear information concerning "any relevant hazards, contraindications, side effects, and precautions." 21 C.F.R. § 801.109(c) (1993). Although these elements are not spelled out in the same detail contained in the regulations governing package inserts for drugs, FDA's guidelines set forth identical categorization and substantiation requirements for device labeling. See ODE Guidance Memorandum G91-1 (March 8, 1991) (on file with the author). Through premarket approval of "Class III" devices (such as pacemakers), FDA establishes detailed requirements regarding the design, manufacture, and labeling of a device in advance of sale. (Most Class I devices (e.g., bandages) and Class II devices (e.g., tampons), as well as some Class III devices for which premarket approval has not yet been required, are subject to premarket notification requirements, and FDA does review labeling when deciding whether a device is "substantially equivalent" to a previously marketed device. See 21 U.S.C. § 360(k) (1988); 21 C.F.R. §§ 807.81-807.97 (1993).) Class labeling requirements for certain devices such as IUDs contemplate the same level of detail as found in prescription drug package inserts. See 21 C.F.R. § 801.427(b)(1) (1993). In the preamble to this regulation, FDA explained that the "Warnings" section "addresses only the most serious of possible adverse effects," and it decided to modify two of the warning statements it had originally proposed, moving one that was less serious into the "Precautions" section and deleting another one altogether because it was not supported by the available data. 42 Fed. Reg. 23,772, 23,774 (1977). Similarly detailed PPIs are mandated for these devices. 21 C.F.R. § 801.427(b)(2) (1993).



### E. *Pesticides and Other Household Products*

A variety of other consumer products must include specific precautionary information in their labeling. CPSC has imposed warning requirements for several different household items that are subject to its jurisdiction, ranging from lawn mowers<sup>180</sup> and charcoal briquettes<sup>181</sup> to baby pacifiers.<sup>182</sup> By contrast, CPSC has designated toys with small parts as banned hazardous substances if intended for use by children under 3 years of age, a prohibition that manufacturers have been able to avoid by including a statement on the label of such toys that they are only recommended for older children.<sup>183</sup> Parents may, however, interpret the age recommendation as based on a developmental standard rather than the risk of choking and may, therefore, be more likely to ignore it.<sup>184</sup>

EPA's authority under FIFRA extends to several types of household products, including general purpose pesticides used by consumers in and around their homes. As FDA has done with many products subject to its jurisdiction, EPA has chosen labeling as its primary means for controlling the marketing and use of pesticides and related products.<sup>185</sup> The Agency has issued detailed regulations governing the use of warning statements in labeling, creating precise matrices linking degrees of human toxicity and other acute risks to warning requirements of different intensity.<sup>186</sup> In many respects, EPA's guidelines

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180. 16 C.F.R. § 1205.6(a) (1993).

181. *Id.* § 1500.14(b)(6)(i) (requiring following boxed warning: "WARNING: Do Not Use for Indoor Heating or Cooking Unless Ventilation is Provided for Exhausting Fumes to Outside. Toxic Fumes May Accumulate and Cause Death.").

182. *Id.* § 1511.7(a) ("[P]acifiers shall be labeled with the statement: 'Warning—Do Not Tie Pacifier Around Child's Neck as it Presents a Strangulation Danger.'").

183. *Id.* pt. 1501. So long as a toy is not marketed or commonly recognized as being intended for children under age three, label recommendations will make the small parts regulation inapplicable to that toy. *See United States v. Toys "R" Us, Inc.*, 754 F. Supp. 1050, 1055 (D.N.J. 1991).

184. *See Toy Mfrs. of America, Inc. v. Blumenthal*, 986 F.2d 615, 619 (2d Cir. 1992); Jean A. Langlois et al., *The Impact of Specific Toy Warning Labels*, 265 JAMA 2848 (1991). A bill recently passed by the House would address this problem by mandating a warning about the risks of choking on the small parts of toys even if recommended for use by children ages three to six. H.R. 965, § 2(a), 103d Cong., 1st Sess. (1993); *see also* S. 680, 103d Cong., 1st Sess. (1993); H.R. REP. NO. 29, 103d Cong., 1st Sess. 4-6 (1993); 58 Fed. Reg. 8013, 8015 (1993) (CPSC decision to withdraw advance notice of proposed rulemaking to require such a warning).

185. *See* 7 U.S.C. § 136(q)(1)(G) (1988) (pesticide labels must include warning and precautionary statements "adequate to protect health and the environment"); *Continental Chemiste Corp. v. Ruckelshaus*, 461 F.2d 331, 335-36 (7th Cir. 1972). EPA requires the use of the following statement on all pesticides: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." 40 C.F.R. § 156.10(i)(2)(ii) (1993).

186. *See id.* § 156.10(h). These requirements generally apply to newly registered pesticides, so revisions to the labeling of older pesticides must await reregistration. In an effort to accelerate labeling revisions, EPA instituted the Label Improvement Program (LIP) in 1980. *See* 45 Fed. Reg. 37,884 (1980). EPA proposed to incorporate in its amendments to the pesticide registration regulations LIP procedures for conforming revisions to labeling in advance of reregistration, 49 Fed. Reg. 37,916, 37,927 (1984), but the proposal was dropped from the final regulation. 53 Fed. Reg. 15,952, 15,963 (1988) ("EPA believes that LIP serves a useful function, with goals of consistency, uniformity; and clarification of labeling . . . [But] regulations for its implementation are premature.").

dictating how and when to convey precautionary information are similar to FDA's regulations governing prescription drug labeling, though EPA's application of its guidelines may be somewhat less rigorous in practice.<sup>187</sup> CPSC regulations governing hazardous substances under the FHSA, though somewhat less detailed, share many of the same characteristics.<sup>188</sup>

EPA's pesticide labeling regulations first set out four human toxicity categories, depending on quantifiable measures of toxicity by different possible routes of exposure. Toxicity Category I would be assigned to a chemical whose LD<sub>50</sub> (median lethal dose in animals) by ingestion occurred at a dose of only 50 mg/kg or lower.<sup>189</sup> Toxicity Categories II and III would be assigned to substances with median lethal doses occurring at doses higher by up to one or two orders of magnitude, respectively. A chemical with an LD<sub>50</sub> exceeding 5000 mg/kg would be assigned to Toxicity Category IV.<sup>190</sup>

A pesticide or similar product assigned to Toxicity Category I must bear the signal word "Danger" on the front panel of the product, along with the word "Poison" if the toxicity results from ingestion, inhalation, or dermal absorption.<sup>191</sup> In addition, first-aid or other instructions for treatment must appear on the front panel of a Category I pesticide.<sup>192</sup> Category II pesticides must bear the signal word "Warning" on their front panel, and all other

187. See W. Kip Viscusi, *Toward a Proper Role for Hazard Warnings in Products Liability Cases*, 13 J. PROD. LIAB. 139, 157-61 (1991) (praising standardization of vocabulary, format, and relative prominence of risk information in drug package inserts, yet criticizing EPA pesticide labeling regulations because of significant variability in approved labeling for similar products); Valle S. Dutcher, *The Marlboro Man Meets the Orkin Man: The Effect of Cipollone v. Ligett Group, Inc. on Federal Preemption by the Federal Insecticide, Fungicide and Rodenticide Act of Failure to Warn Claims Brought under State Tort Law*, 15 J. PROD. & TOXICS LIAB. 29, 38 (1993) ("[F]ederal regulation of pesticides should not allow manufacturers to escape liability for inadequate labeling by 'laundering' the label through the EPA registration process.").

188. See 16 C.F.R. § 1500.3(b)(14)(i) (1993). Canada applies similar labeling requirements to hazardous substances. See Consumer Chemicals and Containers Regulations, C. Gaz. 88-556, pts. III & IV (requiring specified signal words, primary and secondary hazard statements, and first-aid instructions). The Canadian regulations are unusual, however, in that they also require uniform hazard symbols reflecting the type and seriousness of acute hazards such as toxicity and corrosiveness. For example, a poisonous substance for which the signal word "Danger" was required would have to include a skull-and-crossbones inside a bold octagonal border; a less poisonous substances for which the signal word "Warning" was required would have to include a skull-and-crossbones inside a bold diamond-shaped border; and a poison for which only a "Caution" was required would use an inverted triangle as a border. See *id.* § 16 & Schedule II; see also Cosmetic Regulations, C.R.C., c.869, § 26 (1990) (requiring use of these symbols for flammability labeling of cosmetics in pressurized containers).

189. 40 C.F.R. § 156.10(h)(1) (1993). CPSC regulations use median lethal doses to define "highly toxic" substances. 16 C.F.R. § 1500.3(b)(6) (1993).

190. 40 C.F.R. § 156.10(h)(1) (1993); see also 40 Fed. Reg. 28,242, 28,257 (1975) (describing the origins of this numerical scale). For effects on the skin and eyes, qualitative measures are used. Thus, Toxicity Category I would be assigned to a chemical that had corrosive effects on the skin. Toxicity Categories II, III, or IV would be assigned if severe, moderate, or mild to slight skin irritation, respectively, remained after 72 hours. 40 C.F.R. § 156.10(h)(1) (1993).

191. 40 C.F.R. § 156.10(h)(1)(i)(A) (1993). CPSC reserves use of the signal word "Danger" for extremely flammable, corrosive, or highly toxic substances, along with the word "Poison" for highly toxic substances. 16 C.F.R. § 1500.3(b)(14)(i)(C)&(H) (1993). A skull-and-crossbones symbol must accompany the word "Poison." *Id.* § 1500.121(b)(5)(i); see also 7 U.S.C. § 136(q)(2)(D)(i) (1988) (under FIFRA, pesticides labeled as poisonous must include the skull-and-crossbones symbol).

192. 40 C.F.R. § 156.10(h)(1)(iii)(A) (1993).

pesticides must use the word "Caution."<sup>193</sup> First-aid instructions for these other toxicity categories need not appear on the front panel,<sup>194</sup> but the front panel of all pesticide products must bear the statement "keep out of reach of children."<sup>195</sup>

EPA's regulations forbid the use of more than one human hazard signal word on the front panel, and a manufacturer cannot use a more alarming signal word than that required (e.g., "Danger" for a Category III pesticide) unless the Agency first determines that such a deviation would be necessary to prevent unreasonable adverse effects.<sup>196</sup> The hierarchy of signal words also is linked to a hierarchy of required precautionary statements that must follow the signal word. Precautionary statements must indicate "the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage."<sup>197</sup> For example, a product assigned to Toxicity Category I by virtue of an LD<sub>50</sub> based on ingestion would have to include something along the following lines after the word "Danger":

Fatal (poisonous) if swallowed. Do not breathe vapor. Do not get in eyes, on skin, or on clothing. In case of accidental ingestion, contact poison control center immediately.<sup>198</sup>

A Category II pesticide would carry a somewhat milder warning ("May be fatal if swallowed . . ."), a Category III pesticide would carry a still milder caution

193. *Id.* § 156.10(h)(1)(i)(B)-(D). Because CPSC does not define intermediate toxicity categories, the signal words for all hazardous substances not qualifying for "Danger" may be either "Warning" or "Caution." 16 C.F.R. § 1500.3(b)(14)(i)(D) (1993).

194. 40 C.F.R. § 156.10(h)(1)(iii)(B) (1993).

195. *Id.* § 156.10(h)(1)(ii). CPSC applies a similar labeling requirement for those hazardous substances subject to its jurisdiction. 16 C.F.R. § 1500.3(b)(14)(j)(l) (1993).

196. 40 C.F.R. § 156.10(h)(1)(i)(E) (1993). It is also noteworthy that EPA prohibits multilingual labeling for pesticides unless the Agency specifically requires it for a certain product. *Id.* § 156.10(a)(3). If the Agency decides that additional text in another language is necessary to protect the public, it may require either all information in labeling appear in the second language or use of an appropriate translation of the phrase "If you cannot read English do not use this product until properly instructed." 40 Fed. Reg. 28,242, 28,251 (1975). This contrasts with the somewhat greater flexibility permitted by FDA. *See supra* note 122.

197. 40 C.F.R. § 156.10(h)(2)(i)(A) (1993). CPSC requires that the signal word on a hazardous product be followed by an affirmative statement of the principal hazard(s), precautionary measures, and first-aid and special handling instructions. 16 C.F.R. § 1500.3(b)(14)(G)-(I) (1993).

198. *See* 40 C.F.R. § 156.10(h)(2)(i)(B) (1993) (matrix depicting typical precautionary statements by toxicity category). CPSC does not provide such detailed guidelines, but it has set forth specific warning label requirements for especially hazardous substances such as diethylene glycol, various petroleum distillates, charcoal, and fireworks. *See* 16 C.F.R. § 1500.14(b) (1993). For instance, the warning for products containing 10% or more of toluene, benzene, or other petroleum distillates is "Danger: Harmful or fatal if swallowed. Call physician immediately." *Id.* § 1500.14(b)(3)(ii). The warning had included the statement "If swallowed, do not induce vomiting," but this was deleted because in some cases the risk of systemic toxicity would be greater than the risk of aspiration from vomiting. 53 Fed. Reg. 3014, 3015 (1988). FDA requires that the labeling for ipecac syrup, an OTC product used to induce vomiting in poisoning emergencies, include the following warning: "Ordinarily, this drug should not be used if strychnine, corrosives such as alkalis (lye) and strong acids, or petroleum distillates such as kerosene, gasoline, coal oil, fuel oil, paint thinner, or cleaning fluid have been ingested." 21 C.F.R. § 201.308(c)(2) (1993).

("Harmful if swallowed. Avoid breathing vapors . . ."), and a Category IV pesticide need not carry any precautionary statement.<sup>199</sup>

EPA's pesticide labeling regulations also specify appropriate warnings for other hazards that may be associated with the use of a product. Under a separate subheading for "Environmental Hazards," for instance, a statement that "This Pesticide is Toxic to Wildlife" would be required if the active ingredient of a product intended for outdoor use had an acute mammalian or avian oral LD<sub>50</sub> of 100 mg/kg or lower.<sup>200</sup> Under a separate subheading for "Physical or Chemical Hazards," different warning statements concerning flammability or explosive characteristics would be required depending on varying flashpoints and whether the product is in a pressurized container.<sup>201</sup> Although EPA's pesticide labeling regulations do not specify appropriate warnings for chronic hazards such as cancer, private organizations have developed standards that closely resemble the EPA framework for acute hazards.<sup>202</sup>

EPA's new warning requirements for products containing or manufactured with ozone depleting substances, implementing a provision of the Clean Air Act Amendments of 1990,<sup>203</sup> are somewhat out of character with the Agency's cautionary labeling requirements for pesticides. Recall that when FDA and CPSC established their CFC warning requirements, EPA had mandated only a simple disclosure statement on pesticide labels.<sup>204</sup> Tracking the language mandated by Congress, EPA's new regulation requires that the following statement accompany affected products:

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199. See 40 C.F.R. § 156.10(h)(2)(i)(B) (1993). In the preamble to its final regulations, EPA rejected comments suggesting that the signal word "Caution" not be required for Category IV products even though no accompanying precautionary statement is required. 40 Fed. Reg. 28,242, 28,252 (1975).

200. 40 C.F.R. § 156.10(h)(2)(ii)(A)&(C) (1993).

201. *Id.* § 156.10(h)(2)(iii). For instance, pesticide products in non-pressurized containers with flashpoints at or below 20° F would have to be labeled as "Extremely flammable. Keep away from fire, sparks, and heated surfaces." Products with flashpoints of 20°-80° F would have to be labeled as "Flammable. Keep away from heat, sparks, and open flame." Products in non-pressurized containers with flashpoints of 80°-150° F would have to carry the following instruction: "Do not use or store near heat or open flame."

202. See J. E. Betso et al., *Hazard Communication: The Case for Category IV "Cancer Information,"* 8 REG. TOXICOL. & PHARMACOL. 219, 220-22 (1988) (discussing ANSI guideline). By contrast, CPSC has issued warning requirements applicable to various products posing chronic health risks. For instance, paint strippers and other adhesive removers should include language along the following lines: "Contains methylene chloride, which has been shown to cause cancer in certain laboratory animals. Risk to your health depends on level and duration of exposure." 52 Fed. Reg. 34,698, 34,702 (1987); see also *Consumer Fed'n of America v. CPSC*, 883 F.2d 1073, 1078-79 (D.C. Cir. 1989) (upholding the Commission's decision not to ban methylene chloride); Richard A. Merrill, *CPSC Regulation of Cancer Risks in Consumer Products: 1972-1981*, 67 VA. L. REV. 1261, 1310-51 (1981) (describing earlier Commission efforts to classify potential carcinogens as banned hazardous substances).

203. See *supra* notes 56-58 and accompanying text.

204. 42 Fed. Reg. 9205 (1977).

WARNING: Contains [or Manufactured with, if applicable] [*insert name of substance*], a substance which harms public health and environment by destroying ozone in the upper atmosphere.<sup>205</sup>

Although the environmental and attenuated public health risks associated with ozone depleting substances would seem to fit more appropriately as an entry in the “Environmental Hazards” section used in pesticide labeling, the information is introduced with a signal word normally reserved by EPA for chemicals that may pose a serious risk of acute toxicity for the immediate user. Some commenters therefore urged deletion of the term “Warning,” but the Agency responded that it could not alter the language required by Congress.<sup>206</sup>

In proposing the regulation, EPA expressly recognized the importance of not interfering with other required labeling information, and the corresponding need to provide manufacturers with flexibility in complying with the new requirement. The Agency concluded, however, that the warning “will not distract consumers from noticing other warnings on the [principal display panel], such as those required by CPSC under the Federal Hazardous Substances Act.”<sup>207</sup> The final regulation codified this expectation: “The warning statement shall not interfere with, detract from, or mar any labeling information required on the labeling by federal or state law.”<sup>208</sup> Notwithstanding its concern about distracting consumers from other information, EPA requested comments about the possibility of using a symbol (shaped as a stop sign with a partial view of the planet Earth) to draw consumer attention to the new warning,<sup>209</sup> but the Agency did not adopt this idea in the final regulation.<sup>210</sup>

FDA and several persons submitted comments to EPA asking that certain prescription drug products containing ozone depleting substances, such as metered dose inhalers (MDIs) used by asthmatic patients, be exempted from the new warning requirement. These commenters argued that the warning could cause such patients to discontinue prescribed therapies at risk to their health.<sup>211</sup> EPA responded that Congress had not provided it with the authority to exempt

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205. 40 C.F.R. § 82.106(a) (1993).

206. 58 Fed. Reg. 8136, 8157 (1993).

207. 57 Fed. Reg. 19,166, 19,172 (1992).

208. 40 C.F.R. § 82.106(c) (1993).

209. 57 Fed. Reg. 19,166, 19,176 (1992) (“To the extent that a symbol makes the label more noticeable and understandable, it would aid consumers in making this [purchase] decision.”).

210. 58 Fed. Reg. 8136, 8157 (1993).

211. *Id.* at 8155; *see also* 58 Fed. Reg. 34,812, 34,814 (1993) (reiterating FDA’s concern that “patients who are concerned about a medical product’s impact on the environment and public health might inappropriately refrain from taking their medication”). FDA’s CFC warning requirements specifically excludes MDIs and related products. 21 C.F.R. § 369.21 (1993) (“The warning for self-pressurized containers that contain a fully halogenated chlorofluorocarbon is not required and *should not be used* for metered-dose adrenergic bronchodilators for oral inhalation and contraceptive vaginal foams.” (emphasis added)); *id.* § 801.425(c); 42 Fed. Reg. 22,019, 22,026 (1977) (explaining that essential uses were exempted from the warning requirement to avoid unduly alarming patients).

essential products, but that it would tailor the requirement to minimize the risk of unduly alarming patients.<sup>212</sup> The final regulation provides that if the full warning appears in the package insert directed to physicians, then the package label or other labeling intended for patients can bear an abbreviated statement that excludes the signal word "Warning" and the phrase "harms public health."<sup>213</sup>

#### F. *Summary*

The above discussion provides representative examples of the types of cautionary statements mandated by the three federal agencies most directly involved in the regulation of consumer product labeling, namely FDA, EPA, and CPSC.<sup>214</sup> A rudimentary taxonomy may be gleaned from these materials. The requirements vary significantly, reflecting in large part some of the basic differences between the product categories. For instance, FDA's reluctance to mandate warnings for food products contrasts with its evident willingness to require all sorts of warnings for cosmetics, perhaps reflecting a perceived dichotomy between essential and nonessential consumer goods.

The differences in the tone and complexity of warnings for OTC products as compared to prescription drugs and devices no doubt reflect perceived differences in the level of sophistication of the target audiences. When FDA prescribes professional labeling for nonprescription drugs, the warnings are more detailed than the consumer labeling for the same products. Conversely, patient package inserts for prescription drugs are less detailed than the labeling intended for physicians, though they present much more carefully differentiated cautionary information than consumer labeling for OTC drug products. Lastly, while package inserts for physicians must contain a "Warning" when sulfiting agents are present, and a "Precaution" for Yellow No. 5, food products need only include ingredient disclosures in such cases. These differences in labeling requirements demonstrate attention by the Agency to relevant differences in audiences and product categories.

Interagency comparisons are also instructive. All three agencies imposed CFC labeling requirements in the late 1970s. FDA and CPSC opted for warnings, while EPA required only an ingredient disclosure statement. The more recent warning mandated by Congress and implemented by EPA for all ozone depleting substances resembles the older CFC warnings imposed by FDA

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212. 58 Fed. Reg. 8136, 8155-56 (1993).

213. 40 C.F.R. § 82.108(c). FDA announced alternative labeling statements for prescription and nonprescription drugs and devices that could be used to satisfy this requirement. 58 Fed. Reg. 34,812, 34,813 (1993) (placing mandatory warnings between two disclaimers).

214. The more limited roles of the FTC and USDA with respect to the labeling of tobacco and meat products, respectively, and BATF's responsibility for implementing the Alcoholic Beverage Labeling Act, are discussed above.

and CPSC. The various instructional warnings imposed by CPSC for hazardous household products are similar to FDA's requirements for OTC drug products, while EPA's detailed hierarchy of cautionary information for pesticide labeling more closely approximates the requirements for prescription pharmaceuticals. Except for FDA with respect to prescription labeling requirements, all three agencies have struggled with the questions of whether and how to disclose information about chronic health risks possibly associated with a product.

The federal government is not alone in requiring that consumer products bear cautionary information in their labeling. As discussed in the next Part, state regulators and courts further complicate efforts to achieve coherence in this area. A more detailed analysis of some of the general shortcomings of these various warning requirements is reserved for Parts IV and V of the Article.

### III. State Warning Requirements

#### A. *State Statutes and Regulations*

Virtually all states have their own versions of the FD&C Act, including similarly broad prohibitions against the misbranding of food, drugs, medical devices, and cosmetics.<sup>215</sup> But apart from an odd assortment of mandatory warnings for specific products, reflecting either peculiar local conditions or the special concerns of state lawmakers, state requirements are quite limited. One exception is the sweeping "right-to-know" initiative pioneered by the State of California which is discussed in Section 2.

##### 1. *Warnings for Specific Products*

States have imposed specific warning requirements on a variety of products. For example, Louisiana has mandated that warnings appear on all raw shellfish produced or sold in the state because of the threat of cholera:

THERE MAY BE A RISK ASSOCIATED WITH CONSUMING RAW SHELLFISH AS IS THE CASE WITH OTHER RAW PROTEIN PRODUCTS. IF YOU SUFFER FROM CHRONIC ILLNESS OF THE LIVER, STOMACH OR BLOOD OR HAVE OTHER IMMUNE DISORDERS, YOU SHOULD EAT THESE PRODUCTS FULLY COOKED.<sup>216</sup>

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215. See, e.g., FLA. STAT. ANN. chs. 499.007, 499.009, 500.11 (Harrison Supp. 1992); TEX. HEALTH & SAFETY CODE ANN. §§ 431.082, 431.112, 431.142 (West 1992).

216. 19 La. Reg. 643 (May 20, 1993).

California has a similar regulation,<sup>217</sup> and FDA is now considering the desirability of a federal warning requirement for raw shellfish.<sup>218</sup> In Connecticut, apricot kernels may not be sold unless they are packaged and labeled with a warning that such kernels contain cyanide and may be fatal if swallowed.<sup>219</sup> In Oregon, foods containing residues of diethylstilbestrol (DES) must carry a warning label to indicate that this synthetic growth hormone has been associated with vaginal cancer and male genital abnormalities.<sup>220</sup>

State warnings also have been imposed for products other than food. OTC drugs are subject to some specific state labeling requirements.<sup>221</sup> Many states have authorized the prescription use of unapproved drugs such as Laetrile (amygdalin) and dimethyl sulfoxide (DMSO) so long as certain warnings are conveyed to patients.<sup>222</sup> A number of states require that retail establishments selling alcoholic beverages post warnings concerning the risk of birth defects.<sup>223</sup> The State of Connecticut recently mandated that toys containing small parts include a warning statement on the label concerning the choking hazard to children under the age of three.<sup>224</sup>

In addition to hazard statements required by state statute or regulation, courts have in some cases imposed detailed warning requirements pursuant to general statutory prohibitions against false and misleading advertising. For instance, one California appellate court recently affirmed a lower court's order

217. FOOD CHEM. NEWS, Dec. 14, 1992, at 22; *see also* Simeon v. Doe, 618 So. 2d 848, 852 (La. 1993) (person who ate raw oysters tainted with vibrio cholera could maintain failure-to-warn claim against sellers); Kilpatrick v. Superior Court, 277 Cal. Rptr. 230, 237 (Cal. Ct. App. 1991) (same); *Don't Eat Raw Oysters, Experts Warn*, WASH. POST, June 4, 1993, at A14 (California and Louisiana require warnings to be posted; State of Florida is drafting similar labeling regulations).

218. FOOD CHEM. NEWS, Feb. 3, 1992, at 28. The Agency appears to be leaning toward educational campaigns directed at vulnerable populations rather than a label warning. *Id.* at 30.

219. CONN. GEN. STAT. § 21a-67 (1989).

220. OR. REV. STAT. § 616.333 (1989); *see also* FOOD CHEM. NEWS, Mar. 1, 1993, at 2 (describing New York proposal to require warning statements in labeling of meat or dairy products derived from animals given bovine somatotropin (BST), a hormone that promotes milk production). FDA recently approved use of BST without any special labeling requirement. 59 Fed. Reg. 6279, 6280 (1994).

221. *See* Mark B. Gelbert, *State Statutes Affecting the Labeling of OTC Drugs: Constitutionality Based on Commerce Clause and Federal Preemption Theories*, 46 FOOD DRUG COSM. L.J. 629, 643-45 (1991); F-D-C REPORTS ("The Tan Sheet"), March 8, 1993, at 7 (describing New York proposal to require that all OTC products be labeled to warn of risks to the elderly).

222. *See, e.g.*, COLO. REV. STAT. § 12-30-113 (1989) (physician must disclose known adverse effects of amygdalin to patients); FLA. STAT. ANN. § 499.035 (1992) (DMSO labeling must warn in boldfaced type: "May be unsafe. Not approved for human use."); N.J. STAT. ANN. § 24:6F-1 (West Supp. 1993) (amygdalin); TEX. HEALTH & SAFETY CODE ANN. § 439.013 (West 1992) (DMSO).

223. *See, e.g.*, ARIZ. REV. STAT. ANN. § 4-261 (West Supp. 1993) ("Warning: Drinking alcoholic beverages, including distilled spirits, beer, coolers and wine, during pregnancy can cause birth defects."); GA. CODE ANN. § 3-1-5 (1990) ("Warning: Drinking alcoholic beverages during pregnancy can cause birth defects."); S.D. CODIFIED LAWS ANN. § 35-4-100 (1992).

224. CONN. GEN. STAT. § 21a-337 (1993). Industry was unsuccessful in arguing that the state's requirement was preempted by federal law. *See* Toy Mfrs. of America, Inc. v. Blumenthal, 986 F.2d 615 (2d Cir. 1992). A few states at one time also imposed CFC warning requirements. *See, e.g.*, 1977 Minn. Laws, ch. 373, § 1(2). Industry succeeded in arguing that the Minnesota law was preempted. *See* Cosmetic, Toiletry & Fragrance Ass'n, Inc. v. Minnesota, 440 F. Supp. 1216, 1220-1225 (D. Minn. 1977), *aff'd*, 575 F.2d 1256 (8th Cir. 1978) (*per curiam*).



requiring that a producer of unpasteurized milk place the following warning on its products for a period of ten years:

WARNING: THIS MILK MAY CONTAIN DANGEROUS BACTERIA. THOSE FACING THE HIGHEST RISK OF DISEASE OR DEATH INCLUDE BABIES, PREGNANT WOMEN, THE ELDERLY, ALCOHOLICS, THOSE WITH CANCER, AIDS OR REDUCED IMMUNITY AND THOSE TAKING CORTISONE, ANTIBIOTICS OR ANTACIDS. QUESTIONS REGARDING THE USE OF RAW CERTIFIED MILK SHOULD BE DIRECTED TO YOUR PHYSICIAN.<sup>225</sup>

Shortly after issuance of the lower court's decision in this case, the State of California Department of Health Services promulgated a regulation mandating a similar warning on raw milk.<sup>226</sup>

## 2. *Right-To-Know Initiatives*

The State of California has pioneered a far-reaching "right-to-know" law affecting most consumer products. In 1986, voters approved a Public Initiative entitled the "Safe Drinking Water and Toxic Enforcement Act of 1986," better known as "Proposition 65."<sup>227</sup> The law was enacted to prevent contamination of water supplies and other toxic environmental exposures.<sup>228</sup> Proposition 65

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225. *Consumers Union v. Alta-Dena Certified Dairy*, 6 Cal. Rptr. 2d 193, 197 (Cal. Ct. App. 1992). In addition, the court had mandated corrective advertising. *Id.* Federal courts have sometimes upheld similar obligations imposed by FTC to correct misleading advertising campaigns. *See, e.g.,* *Porter & Dietsch, Inc. v. FTC*, 605 F.2d 294, 306-07 (7th Cir. 1979) (advertising of nonprescription weight loss tablets), *cert. denied*, 445 U.S. 950 (1980); *Warner-Lambert Co. v. FTC*, 562 F.2d 749, 763 (D.C. Cir. 1977) (advertising had to include warning that mouthwash product does not yield previously advertised health benefits), *cert. denied*, 435 U.S. 950 (1978). Companies have on occasion brought unfair competition claims alleging that competitors have provided inadequate warnings on their products, but courts generally have rejected such claims. *See, e.g.,* *American Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 143-45 (S.D.N.Y. 1987) (rejecting claims brought under Lanham Act and New York's unfair competition and deceptive advertising laws alleging that labeling of aspirin product had unlawfully diluted prominence of FDA's Reye syndrome warning).

226. *See* CAL. CODE REGS. tit. 17, § 11380 (1993); *see also* FOOD CHEM. NEWS, Nov. 22, 1993, at 62 (describing Oregon's proposal to require similar warnings). In response to a court order, *Public Citizen v. Heckler*, 653 F. Supp. 1229, 1241 (D.D.C. 1986), FDA promulgated regulations prohibiting the interstate sale of raw milk. 21 C.F.R. § 1240.61 (1993); *see also* 52 Fed. Reg. 29,509, 29,513 (1987) (rejecting cautionary labeling as an alternative).

227. CAL. HEALTH & SAFETY CODE §§ 25249.5-.13 (1992). *See generally* Paulette L. Stenzel, *Right-To-Know Provisions of California's Proposition 65: The Naivete of the Delaney Clause Revisited*, 15 HARV. ENVTL. L. REV. 493 (1991); Melinda Haag, Note, *Proposition 65's Right-To-Know Provision: Can It Keep Its Promise to California Voters?*, 14 ECOLOGY L.Q. 685 (1987).

228. Congress has enacted similar "right-to-know" laws involving potential exposures to toxic substances. *See* 42 U.S.C. § 11044(a) (1988) ("Each emergency response plan, material safety data sheet, . . . [and] toxic chemical release form . . . shall be made available to the general public"). This provision was part of the Emergency Planning and Community Right-to-Know Act, included in the Superfund Amendments and Reauthorization Act of 1986, Pub. L. No. 99-499, title III, 100 Stat. 1728 (1986).

also included controversial consumer product warning requirements that had the dual purpose of educating consumers and encouraging companies to reformulate their products. Although there is little evidence suggesting that the warnings have had much of a direct impact on consumer behavior, the State has been able to force several manufacturers to reformulate their products.<sup>229</sup>

Proposition 65 provides that "[n]o person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual . . . ."<sup>230</sup> An implementing regulation creates safe harbors if certain statements are used when appropriate, such as "WARNING: This product contains a chemical known to the State of California to cause cancer."<sup>231</sup> The law states that warnings "may be provided by general methods such as labels on consumer products, . . . posting of notices, placing notices in the public news media, and the like, provided that the warning accomplished is clear and reasonable."<sup>232</sup>

Warnings are not required for exposures to listed chemicals shown to pose either "no significant risk" of cancer or, in the case of reproductive toxicants, "no observable effect" at an exposure 1000 times higher than expected.<sup>233</sup> "No significant risk" is defined as less than one excess cancer in a population of

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Similarly, the Occupational Safety and Health Administration (OSHA) enforces a hazard communication standard for exposures in the workplace. See 29 C.F.R. § 1910.1200 (1993).

229. See Marina Gatti, *Proposition 65: "Shoot First, Ask Questions Later" -vm-Do the Bullets Really Work? Have We Shot the Wrong Party? Will They Call Out the Bazookas?*, 47 FOOD & DRUG L.J. 739, 741 nn.14-17 (1992). In 1989, for example, the Gillette Company agreed to reformulate its correction fluid product "Liquid Paper" after the State instituted legal action alleging a failure to warn of the presence of trichloroethylene, a chemical listed as a reproductive toxicant. Office of the Cal. Atty. Gen., *Proposition 65 Litigation*, at 3 (Jan. 15, 1993) (on file with the author). In 1992, American Home Products Corporation agreed to reformulate its OTC product "Preparation H" by removing phenyl mercuric nitrate. *Id.* at 14.

230. CAL. HEALTH & SAFETY CODE § 25249.6(1992). The governor must publish and periodically update a list of chemicals known to cause cancer or reproductive toxicity, based on findings made by other organizations. *Id.* § 25249.8. The list has grown to almost 300 carcinogens and more than 100 reproductive toxicants. See Cal. Regulatory Notice Reg. 92, No. 13-Z (1992), at 376.

231. The other statements include the following:

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

WARNING: Chemicals known to the State of California to cause cancer, or birth defects or other reproductive harm may be present in foods or beverages sold or served here.

WARNING: Drinking Distilled Spirits, Beers, Coolers, Wine and Other Alcoholic Beverages May Increase Cancer Risk, and, During Pregnancy, Can Cause Birth Defects.

CAL. CODE REGS. tit. 22, § 12601(b)(4) (1993). The labeling for fresh produce must include the following warning: "This product may contain a chemical known to the State of California to cause cancer, or birth defects or other reproductive harm." *Id.* § 12601(b)(4)(D) (emphasis added).

232. CAL. HEALTH & SAFETY CODE § 25249.11(f) (1992). Nonetheless, efforts to rely on non-label methods of warning, such as a toll-free telephone information hotline, have been judged to be inadequate. See Ingredient Communication Council, Inc. v. Lungren, 4 Cal. Rptr. 2d 216 (1992).

233. CAL. HEALTH & SAFETY CODE § 25249.10(c) (1992).

100,000 exposed over a lifetime.<sup>234</sup> FDA-approved labeling for prescription drugs satisfies the warning requirement.<sup>235</sup> By an interim regulation, California also had determined that other FDA-regulated products are not subject to the warning requirements.<sup>236</sup> Although only an interim exemption pending the completion of quantitative risk assessments to establish "no significant risk" levels for individual chemicals, this regulation had been considered essential for avoiding the absurd result that would follow if Proposition 65 were held to require warnings on all consumer products whose safety was already accepted by federal and state regulatory agencies. The State recently revoked the exemption,<sup>237</sup> however, so a number of consumer products soon may have to include Proposition 65 warnings in their labeling.

Several other states have considered legislation modeled on Proposition 65,<sup>238</sup> but all such proposals have been rejected to date. For instance, a similar ballot initiative in Ohio recently was defeated by a significant margin.<sup>239</sup> Even if none of these other state "right to know" proposals are adopted, Proposition 65 will continue to have a pronounced effect on how manufacturers convey warnings about chronic health risks. In fact, because of the practical difficulties with separate systems for in-state labeling and distribution, Proposition 65 warnings appear on products sold outside of California.

#### B. *The Duty to Warn Under State Tort Law*

Compliance with the many requirements imposed by Congress, federal regulatory agencies, and state governments does not exhaust a manufacturer's potential duty to warn. Notwithstanding the often pervasive regulation of the content of consumer product labeling, courts have allowed plaintiffs to recover

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234. CAL. CODE REGS. tit. 22, §§ 12703(b), 12711(a)(1) (1993). Assuming an average life span of 70 years, this converts to an annual risk of cancer of one in seven million. This is less than the proverbial chance of getting struck by lightning. See EDMUND A.C. CROUCH & RICHARD WILSON, *RISK/BENEFIT ANALYSIS* 176 (1982) (citing annual per capita risk of being struck by lightning as one in two million).

235. CAL. CODE REGS. tit. 22, § 12601(b)(2) (1993). In addition, products containing naturally occurring carcinogens need not carry a warning. *Id.* § 12501(a). This regulation was upheld in *Nicolle-Wagner v. Deukmejian*, 281 Cal. Rptr. 494, 498 (1991).

236. CAL. CODE REGS. tit. 22, § 12713(a) (1993) ("[E]xposure to a listed chemical in a food, drug, cosmetic or medical device which is in compliance with state and federal administrative standards applicable to the product in question poses no significant risk as described in this section."). No comparable exemption was provided for reproductive toxicants, however, such as aspirin. See Cal. Regulatory Notice Reg. 92, No. 13-Z (1992), at 384. Thus, products containing aspirin may need to be accompanied by a Proposition 65 warning in addition to FDA's general pregnancy warning for OTC drug products and specific third-trimester pregnancy warning for products containing aspirin. See *supra* note 125 and accompanying text.

237. See F-D-C REPORTS ("The Tan Sheet"), Jan. 3, 1994, at 38; M-D-D-I REPORTS ("The Gray Sheet"), Dec. 13, 1993, at 19.

238. See Gatti, *supra* note 229, at 744 n.29 (citing recent legislative proposals in Massachusetts, Illinois, New York, Missouri, and Oregon); Jerome H. Heckman, *California's Proposition 65: A Federal Supremacy and States' Rights Conflict in the Health and Safety Arena*, 43 FOOD DRUG COSM. L.J. 269, 277-78, 281 (1988) (citing proposals in Tennessee, Hawaii, Missouri, New York, Illinois, and Massachusetts).

239. See F-D-C REPORTS ("The Rose Sheet"), Nov. 9, 1992, at 3 (rejected by 78% of the voters).

for injuries allegedly stemming from a manufacturer's failure to provide adequate warnings of certain product risks. With the benefit of hindsight, juries frequently hold a manufacturer liable for not warning against the particular injury suffered by the plaintiff. Moreover, even when a warning has been provided, judges and juries may decide that the cautionary information should have been made more prominent or alarming.

In products liability litigation, failure-to-warn claims have become quite common, supplanting the more traditional and difficult to prove claims such as those alleging defects in manufacture or design.<sup>240</sup> Although prescription drugs by their very nature are most often the subject of lawsuits alleging failures to warn, no consumer good is immune from such products liability claims. Other products that have been faulted for not providing adequate warnings include cosmetics,<sup>241</sup> food products,<sup>242</sup> nonprescription drugs,<sup>243</sup> medical devices,<sup>244</sup> pesticides and herbicides,<sup>245</sup> and common tools or appliances.<sup>246</sup> The most difficult questions in all of these cases are whether there is a duty to warn of a particular risk and, if there is such a duty, how one decides whether any warning that was provided is adequate.

240. See James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 267-69 (1990). Claims alleging that a product was defective in its design or manufacture are less common. See, e.g., *Tobin v. Astra Pharmaceutical Products, Inc.*, 993 F.2d 528, 540 (6th Cir. 1993) (upholding design defect verdict against manufacturer of FDA-approved drug because "a reasonably prudent manufacturer would not market [the drug] if the evidence of its efficacy was inconclusive"); *Ezagui v. Dow Chemical Corp.*, 598 F.2d 727 (2d Cir. 1979) (preservative used in quadrivalent vaccine activated dangerous pertussis component).

241. See, e.g., *Gober v. Revlon, Inc.*, 317 F.2d 47, 51 (4th Cir. 1963) (sustaining verdict for plaintiff who suffered allergic reaction to nail polish product); *Whitehurst v. Revlon, Inc.*, 307 F. Supp. 918, 920-21 (E.D. Va. 1969) (adequacy of flammability warning for nail polish was properly left to jury); *Moran v. Fabergé, Inc.*, 332 A.2d 11, 21 (Md. 1975) (reinstating jury verdict for plaintiff when manufacturer's cologne ignited over a candle).

242. See, e.g., *Fraust v. Swift & Co.*, 610 F. Supp. 711, 714 (W.D. Pa. 1985) (denying peanut butter manufacturer's motion for summary judgment against claim alleging failure to warn of choking hazard for young children); *Allen v. Delchamps, Inc.*, 624 So. 2d 1065, 1068-69 (Ala. 1993) (grocer could be liable for selling fresh produce containing undisclosed sulfites); *Barry v. Don Hall Laboratories*, 642 P.2d 685, 691 (Or. Ct. App. 1982) (jury could find manufacturer liable for failing to warn that high sugar content of vitamin C product, when combined with ascorbic acid, could lead to tooth decay).

243. See, e.g., *Hahn v. Sterling Drug, Inc.*, 805 F.2d 1480, 1482-83 (11th Cir. 1986) (topical analgesic); *Torsiello v. Whitehall Laboratories*, 398 A.2d 132, 137-40 (N.J. Super. Ct. App. Div. 1979) (aspirin products), *cert. denied*, 404 A.2d 1150 (N.J. 1979); *Michael v. Warner/Chilcott*, 579 P.2d 183, 187 (N.M. Ct. App. 1978) (sinus medication).

244. See, e.g., *O'Gilvie v. International Playtex, Inc.*, 821 F.2d 1438, 1441-43 (10th Cir. 1987) (tampons), *cert. denied*, 486 U.S. 1032 (1988); *Desmarais v. Dow Corning Corp.*, 712 F. Supp. 13, 14 (D. Conn. 1989) (silicone breast implants); *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1027 (D.N.J. 1988) (intrauterine devices); *Strothkamp v. Chesebrough-Pond's Inc.*, 1993 Mo. App. LEXIS 417 (March 23, 1993) (manufacturer of Q-Tips could be held liable for failure to warn of risk of injuring ear drum).

245. See, e.g., *Burke v. Dow Chemical Co.*, 797 F. Supp. 1128, 1133 (E.D.N.Y. 1992) (household insecticide); *Boyl v. California Chemical Co.*, 221 F. Supp. 669, 675-76 (D. Or. 1963) (residential herbicide); *Gainey v. Perkins*, 500 So. 2d 272, 273 (Fla. Dist. Ct. App. 1986) (rat poison).

246. See, e.g., *Chappuis v. Sears Roebuck & Co.*, 358 So. 2d 926, 928-30 (La. 1978) (hammer); *Post v. American Cleaning Equip. Co.*, 437 S.W.2d 516, 520 (Ky. Ct. App. 1969) (vacuum cleaner).

Manufacturers have a duty to alert users of a product to dangers of which the manufacturer is or should be aware.<sup>247</sup> Manufacturers need not warn consumers of dangers that are generally known and recognized.<sup>248</sup> At the other extreme, the duty to warn of non-obvious risks only arises after the manufacturer learns or should have learned of the hazard.<sup>249</sup> It is difficult, of course, to identify at what point knowledge about a putative hazard gives rise to a duty to warn. Some courts have found such a duty on the basis of extremely weak evidence that a substance may have caused an injury,<sup>250</sup> while others have demanded greater substantiation of a risk allegedly posed by a product before imposing a duty to warn of that risk.<sup>251</sup> In any event, manufacturers must warn of the hazards associated with both the intended use and any foreseeable misuse of a product.<sup>252</sup> It is generally no defense that a

247. See *Feldman v. Lederle Laboratories*, 479 A.2d 374, 388 (N.J. 1984); RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (1965).

248. See, e.g., *Kuras v. International Harvester Co.*, 820 F.2d 15, 18 (1st Cir. 1987) (manufacturer of lawn mower had no duty to warn against placing hand into spinning blade); *Garrison v. Heublein, Inc.*, 673 F.2d 189, 192 (7th Cir. 1982) ("[T]he dangers of the use of alcohol are common knowledge to such an extent that the product cannot objectively be considered to be unreasonably dangerous."); *Glittenberg v. Doughboy Recreational Ind.*, 491 N.W.2d 208, 214 n.15 (Mich. 1992); cf. *Hon v. Stroh Brewery Co.*, 835 F.2d 510, 515 (3d Cir. 1987) (warning may have been necessary concerning some of lesser known risks of prolonged alcohol consumption, such as pancreatitis).

249. See, e.g., *Hermes v. Pfizer, Inc.*, 848 F.2d 66, 68 (5th Cir. 1988); *Castignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 782 (R.I. 1988) (refusing to hold manufacturer of DES liable "for failure to warn of risks inherent in a drug [because] it neither knew nor could have known by the application of scientific knowledge available at the time of distribution that the drug could produce the undesirable effects suffered by plaintiff"); *Griggs v. Combe, Inc.*, 456 So. 2d 790, 792 (Ala. 1984) (OTC drug manufacturer "had no duty to warn of a possible allergic reaction which it had no reason to suspect might occur").

250. See, e.g., *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741, 745-46 (11th Cir.) (manufacturer of spermicide had duty to warn of possible teratogenicity notwithstanding FDA's conclusion that these drugs did not cause birth defects), *cert. denied*, 479 U.S. 950 (1986); *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1535-38 (D.C. Cir.) (anecdotal evidence of pulmonary fibrosis resulting from dermal absorption of herbicide paraquat created a duty to warn), *cert. denied*, 469 U.S. 1062 (1984); *Roberts v. United States*, 316 F.2d 489, 495 (3d Cir. 1963) (finding that plaintiff's injury being the first one reported where animal and human data generally showed toxicity concerns did not necessarily preclude liability).

251. See, e.g., *Doe v. Miles Laboratories, Inc.*, 927 F.2d 187, 194 (4th Cir. 1991) (no duty to warn where "only one case of AIDS was reported that could possibly have been related to Factor IX treatment . . . [and] only a few AIDS cases were related to the use of any blood factor concentrate"); *Novak v. United States*, 865 F.2d 718, 726 (6th Cir. 1989) (warnings accompanying swine flu vaccine not inadequate for failing to alert persons of risk of autoimmune disease because there was "insufficient medical evidence" of causation); *Smith v. Ortho Pharmaceutical Corp.*, 770 F. Supp. 1561, 1582 (N.D. Ga. 1991) (rejecting failure-to-warn claim because there was no "reasonably reliable" evidence that spermicide caused birth defects); *Finn v. G.D. Searle & Co.*, 677 P.2d 1147, 1153 (Cal. 1984) ("Knowledge of a potential side effect which is based on a single isolated report of a possible link between a prescription drug and an injury may not require a warning.").

252. See, e.g., *Knowlton v. Deseret Medical, Inc.*, 930 F.2d 116, 122-23 (1st Cir. 1991) (device manufacturer knew catheter was being used in open-heart surgery); *Sutherland v. Elpower Corp.*, 923 F.2d 1285, 1289 (8th Cir. 1991) (toy manufacturer could be held liable for failure to warn about "reasonably foreseeable, albeit unintended, uses" of its product); *Johnson v. Husky Industries, Inc.*, 536 F.2d 645, 648 (6th Cir. 1976) (manufacturer of charcoal briquets could be held liable for inadequately warning against indoor use for heating); RESTATEMENT (SECOND) OF TORTS § 395 cmt. k (1965) ("The manufacturer may . . . reasonably anticipate other uses than the one for which the chattel is primarily intended."); cf. *Berg v. Underwood's Hair Adaptation Process, Inc.*, 751 F.2d 136, 137 (2d Cir. 1984) (manufacturer of synthetic fibers for wigs had no duty to warn against misuse of fibers as implants for scalp); *Ferlito v. Johnson & Johnson Products, Inc.*, 771 F. Supp. 196, 200 (E.D. Mich. 1991) (Plaintiffs "failed to demonstrate the

plaintiff's injury resulted from misuse if the manufacturer was aware that such misuse might take place and could have warned against it.

Another factor relevant to whether a duty to warn exists is the magnitude of the risk posed by the product. Manufacturers generally do not have a duty to warn of risks that may affect only very few individuals,<sup>253</sup> but courts sometimes hold otherwise in cases where the manufacturer knows that hypersensitive individuals may suffer serious injury.<sup>254</sup> In one case, the court held that the manufacturer had a duty to warn of the less than one-in-a-million risk of contracting polio from a vaccine because the risk of contracting polio as a result of not using the vaccine was equally small.<sup>255</sup>

In essentially all jurisdictions, manufacturers of prescription drugs satisfy their common law duty to warn by providing precautionary information to physicians and others who act as "learned intermediaries."<sup>256</sup> This rule exists because "the choice involved [in prescribing a particular medication] is essentially a medical one involving an assessment of medical risks in light of the physician's knowledge of this patient's needs and susceptibilities."<sup>257</sup> Only in situations where such an individualized decision is unlikely to be made (for example, when drugs are being administered to patients in a mass immunization program) would a manufacturer have to provide a warning directly to the pa-

foreseeability of an adult male encapsulating himself from head to toe in cotton batting and then lighting up a cigarette."), *aff'd mem.*, 983 F.2d 1066 (6th Cir. 1992).

253. See *Adelman-Tremblay v. Jewel Companies, Inc.*, 859 F.2d 517, 521 (7th Cir. 1988) ("[I]n the majority of jurisdictions [there is] no duty to warn of the possibility of a rare and unusual allergic reaction."); *Burlison v. Warner-Lambert Co.*, 842 F.2d 991 (8th Cir. 1988) (cough drop manufacturer had no duty to warn in absence of evidence it knew or should have known of possible allergic reactions); *Mountain v. Procter & Gamble Co.*, 312 F. Supp. 534, 537 (D. Wis. 1970) (no duty to warn of severe allergic reaction to shampoo experienced by a "miniscule percentage" of users); *Kaempfe v. Lehn & Fink Prods. Corp.*, 249 N.Y.S.2d 840, 845 (N.Y. App. Div. 1964) ("We have not yet reached . . . the point where the manufacturer is under the absolute duty of giving special warning against a remote possibility of harm due to an unusual allergic reaction"), *aff'd*, 284 N.Y.S.2d 708 (N.Y. 1967).

254. See *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 430 (2d Cir. 1969) (drug manufacturer has duty to warn those few persons whom it knows cannot apply its product without serious injury); *Wright v. Carter Products*, 244 F.2d 53, 58 (2d Cir. 1957) (manufacturer of deodorant that caused contact dermatitis in a small number of users may have "to warn those few persons who it knows cannot apply its product without serious injury"); *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 530 (Or. 1974); *Tomer v. American Home Products Corp.*, 368 A.2d 35, 40 (Conn. 1976).

255. *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 130 n.16 (9th Cir. 1968). *But see* *Kearl v. Lederle Laboratories*, 218 Cal. Rptr. 453, 468 (Cal. Ct. App. 1985) ("[W]hatever duty a manufacturer may have to inform of risks associated with nonuse of a product, such a duty most certainly cannot be imposed when the relationship between use and nonuse is statistically close (and quite possibly immeasurable) and the probability of injury from either course is extremely remote."); *Calabrese v. Trenton State College*, 392 A.2d 600, 604 (N.J. Sup. Ct. App. Div. 1978), *aff'd*, 413 A.2d 315 (N.J. 1980).

256. See, e.g., *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 811 (5th Cir.), *cert. denied*, 112 S. Ct. 2304 (1992); *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978, 992 (8th Cir. 1969); *Wyeth Laboratories, Inc. v. Fortenberry*, 530 So. 2d 688, 691-92 (Miss. 1988).

257. *Davis*, 399 F.2d at 130; see also *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231-32 (4th Cir. 1984) (manufacturer of cardiac pacemaker satisfied duty to warn of dislodgement risk by alerting physicians).

tient.<sup>258</sup> A few courts have extended the mass immunization exception to other drugs, such as contraceptives, for which a physician may not make an individualized judgment in prescribing a particular medication.<sup>259</sup>

If a duty to warn does exist in a particular case, the complete failure to provide any warning of the risk would represent an actionable breach. The question becomes more difficult when a manufacturer has conveyed a warning of the risk in question but the plaintiff alleges that the warning was inadequate. When a product's labeling warns of the very injury suffered by the plaintiff in clear and precise terms, the manufacturer usually will be entitled to summary judgment.<sup>260</sup> In at least one case, however, a court has held that a warning label might be inadequate even if the risk of the very injury suffered by the plaintiff was clearly disclosed, on the grounds that the plaintiff might have been deterred from taking the drug had the risk of some other more serious injury been adequately disclosed.<sup>261</sup>

One court offered the following guidance for judging whether a warning is adequate:

[F]irst, it must be in such form that it could reasonably be expected to catch the attention of the reasonably prudent man in the circumstances of its use; secondly, the content of the warning must be of such a nature as to be comprehensible to the average user and to convey a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person.<sup>262</sup>

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258. See *Plummer v. Lederle Laboratories*, 819 F.2d 349, 356 (2d Cir.) ("If the drug is given under clinic-type conditions the manufacturer is obligated to warn consumers directly."), *cert. denied*, 484 U.S. 898 (1987); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276-77 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

259. See, e.g., *Hill v. Searle Laboratories*, 884 F.2d 1064, 1071 (8th Cir. 1989) (IUDs); *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 69-70 (Mass.) (oral contraceptives), *cert. denied*, 474 U.S. 920 (1985). But see *Haste v. American Home Products Corp.*, 577 F.2d 1122, 1124-25 (10th Cir.), *cert. denied*, 439 U.S. 955 (1978); *Skill v. Martinez*, 91 F.R.D. 498, 507 (D.N.J. 1981), *aff'd*, 677 F.2d 368 (3d Cir. 1982); *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 840 (Ohio 1981).

260. See, e.g., *Brick v. Barnes-Hines Pharmaceutical Co.*, 428 F. Supp. 496, 498 (D.D.C. 1977); *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102, 105 (Fla. 1989); *Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1325-26 (Kan. Ct. App. 1986), *aff'd*, 758 P.2d 206 (Kan. 1988).

261. *Sanderson v. Upjohn Co.*, 578 F. Supp. 338, 339-40 (D. Mass. 1984); see also *McMahon v. Eli Lilly & Co.*, 774 F.2d 830, 834-35 (7th Cir. 1985).

262. *Spruill v. Boyle-Midway, Inc.*, 308 F.2d 79, 85 (4th Cir. 1962) ("If warning of the danger is given and this warning is of a character reasonably calculated to bring home to the reasonably prudent person the nature and extent of the danger, it is sufficient to shift the risk of harm from the manufacturer to the user."); see also *Bloxom v. Bloxom*, 512 So. 2d 839, 844 (La. 1987); *Richards v. Upjohn Co.*, 625 P.2d 1192, 1196 (N.M. App. 1980). Warnings may serve either instructional or informative purposes. *Finn v. G.D. Searle & Co.*, 677 P.2d 1147, 1152 (Cal. 1984); see also W. PAGE KEETON, PROSSER & KEETON, *THE LAW OF TORTS* § 96 (5th ed. 1984), at 685 (the two goals of warnings are "risk reduction and the protection of individual autonomy in decision-making").

Thus, courts generally require that a warning be communicated with the degree of urgency necessary to cause the user to exercise the level of caution commensurate with the potential danger.<sup>263</sup> For instance, plaintiffs in drug cases will sometimes complain that a side effect listed in the Adverse Reactions section should instead have appeared in the Warnings or even Contraindications section of the package insert. A warning also may be judged inadequate if its tone, placement, or typeface makes it unlikely to attract the user's attention.<sup>264</sup> The use of qualifying language may dilute the impact of an otherwise satisfactory warning,<sup>265</sup> or such a warning may be rendered inadequate by a manufacturer's over-promotion of the product.<sup>266</sup>

Several courts have held that a warning "must communicate the specific danger and risk, including the likelihood and severity of injury,"<sup>267</sup> but a manufacturer generally need not catalog every possible consequence of such an injury.<sup>268</sup> In one case involving labeling for oral contraceptives, however,

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263. See *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1363 (4th Cir. 1975); *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 837 (Ohio 1981) ("A reasonable warning not only conveys a fair indication of the nature of the dangers involved, but also warns with the degree of intensity demanded by the nature of the risk."); *Tampa Drug Co. v. Wait*, 103 So. 2d 603, 609 (Fla. 1958); *Richards*, 625 P.2d at 1196 ("[T]he drug manufacturer must bring the warning home to the doctor."); *Post v. American Cleaning Equip. Corp.*, 437 S.W.2d 516, 520 (Ky. Ct. App. 1969) (voltage instructions on vacuum cleaner failed to describe the potentially serious consequences of ignoring the instructions).

264. See *Spruill*, 308 F.2d at 86 (warning on furniture polish "was placed so as to conceal it from all but the most cautious users. It is located in the midst of a body of print of the same size and color, with nothing to attract special attention to it except the words 'Safety Note.'"); *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978, 994 (8th Cir. 1969) ("The 'Dear Doctor' letter could have been reasonably found to be lacking in emphasis, timeliness and attention inviting qualities. . . . [I]ts wording, and the manner of its circulation could be found unreasonable considering the magnitude of the risk involved."); *Walker v. Maybelline Co.*, 477 So. 2d 1136, 1139 (La. Ct. App. 1985) ("The [mascara] warning was buried in a list of instructions with nothing to call it to the attention of the purchaser. Moreover, it started with the word 'Note', which would not call the reader's attention to the grave nature of the threat. Furthermore, no mention was made of the threat of *pseudomonas* infection or of eye infection with possible resultant loss of eyesight."), *cert. denied*, 481 So. 2d 1333 (La. 1986).

265. See, e.g., *Tinnerholm v. Parke, Davis & Co.*, 285 F. Supp. 432, 451 (S.D.N.Y. 1968) (finding that a warning had been "water[ed] down" by the "shrewd use of descriptive adjectives"), *modified*, 411 F.2d 48 (2d Cir. 1969); *Maize v. Atlantic Refining Co.*, 41 A.2d 850, 851 (Pa. 1945) (prominent use of brand name "Safety-Kleen" diverted attention from caution against using product in poorly ventilated areas); *McFadden v. Haritatos*, 448 N.Y.S.2d 79, 81 (N.Y. App. Div. 1982) (statement that 'side effects of drug are usually reversible' "tends to qualify and dilute the whole of the [adverse reactions] section's admonition."); *Ross v. Jacobs*, 684 P.2d 1211, 1215-16 (Okla. Ct. App. 1984).

266. See, e.g., *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1363-64 (4th Cir. 1975); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661-62 (Cal. 1973); *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971). Agencies are also cognizant of this problem. See, e.g., 41 Fed. Reg. 38,312, 38,334 (1976) (FDA panel reviewing OTC antihistamines strongly urged FTC to challenge any advertisement which "[i]n any way negates or dilutes the information on the label, especially the contraindications and/or warnings").

267. *McHargue v. Stokes Div. of Pennwalt*, 686 F. Supp. 1428, 1437 n.8 (D. Colo. 1988); see also *Cooley v. Carter-Wallace, Inc.*, 478 N.Y.S.2d 375, 379-80 (App. Div. 1984) ("Mere directions for the proper use of a product which fail to warn of specific dangers and risks of harm if the directions are not followed may be inadequate.").

268. See *Jamieson v. Woodward & Lothrop*, 247 F.2d 23, 25 & 30 (D.C. Cir.) (en banc) (exercise rope hit plaintiff's eye causing retina to detach), *cert. denied*, 355 U.S. 855 (1957); *Vallillo v. Muskin Corp.*, 514 A.2d 528, 531 n.3 (N.J. 1986) ("It is generally sufficient if the warning gives general notice of a danger and the conduct to be avoided. For example, signs giving a warning of high voltage electricity that pictorially indicate not to touch wires . . . need not indicate the particular permanent physical harm that



warnings emphasizing the risk of "fatal" adverse reactions but failing to use the word "stroke" were found potentially inadequate because a jury might conclude that the resulting permanent disability is a fate worse than death.<sup>269</sup> Product labeling also must include clear instructions for avoiding or minimizing the risk.<sup>270</sup>

Normally the adequacy of a warning is judged by an objective standard which refers to a hypothetical average consumer rather than the particular plaintiff. However, some courts use a more subjective standard and ask whether a warning is comprehensible to persons like the plaintiff. The duty to warn then becomes difficult to satisfy with respect, for instance, to consumers who cannot read English. A few courts have suggested that the failure to provide warnings in Spanish may be actionable,<sup>271</sup> or that labeling must include pictograms for persons who cannot read no matter what language they speak.<sup>272</sup>

Even a specific and prominent warning may be found inadequate if it has not been communicated through the most effective channels. For instance, a number of courts have demanded the use of methods other than labeling to convey information to physicians about prescription drug risks, in part because

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might befall a person who disregards the warning.").

269. *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 72 (Mass.), *cert. denied*, 474 U.S. 920 (1985); *see also Petty v. United States*, 740 F.2d 1428, 1437 (8th Cir. 1984) ("[T]he risk of death may be conceptually remote, whereas a more specific warning detailing the known risk of serum sickness and its symptoms would alert recipients more concretely to the risks that they actually were assuming."). *But see Mampe v. Ayerst Laboratories*, 548 A.2d 798, 801 (D.C. App. 1988) ("We seriously doubt that promotional materials which warn of death as a possible reaction to a drug could be inadequate to warn of a consequence any less severe."); *Dunkin v. Syntex Laboratories, Inc.*, 443 F. Supp. 121, 124 (W.D. Tenn. 1977) (warnings that oral contraceptive created risk of thrombosis, cerebral vascular accident, and fatal blood clotting abnormalities held to be adequate).

270. *See, e.g., Tucson Industries, Inc. v. Schwartz*, 487 P.2d 12, 18 (Ariz. Ct. App. 1971) (instruction to provide "adequate ventilation" when using adhesive was ambiguous); *Burch v. Amsterdam Corp.*, 366 A.2d 1079, 1086 (D.C. App. 1976) (a warning is inadequate unless it "provides *specific* directions for safe use"). The court in *Burch* decided that a prominent flammability warning on an adhesive product (using language required under the FHSA) may not have adequately alerted a person against using it near a pilot light. *Id.* at 1087-88.

271. *Stanley Industries, Inc. v. W.M. Barr & Co.*, 784 F. Supp. 1570, 1576 (S.D. Fla. 1992) (manufacturer of linseed oil product may have owed plaintiffs a duty to warn in Spanish or through pictorial warning symbols where company advertised product in local Hispanic media and a large percentage of the foreseeable users only spoke Spanish); *Ramirez v. Plough, Inc.*, 12 Cal. Rptr. 2d 423, 430 (Cal. Ct. App. 1992) (jury allowed to decide whether aspirin manufacturer should have reasonably foreseen use of the product by non-English speaking individuals, and if so whether warning should have included language other than English), *rev'd*, 25 Cal. Rptr. 2d 97 (1993). Similarly, one court apparently was persuaded by the argument that more explicit and prominently placed warnings may be necessary for products used by youngsters "mindful of teenagers' inclination not to follow instructions." *Nowak v. Fabergé U.S.A., Inc.*, 812 F. Supp. 492, 497 (M.D. Pa. 1992).

272. *See Hubbard-Hall Chemical Co. v. Silverman*, 340 F.2d 402, 405 (5th Cir. 1965) (even though pesticide label had been approved by USDA, a jury could find the warning inadequate for users who did not speak English "because of its lack of a skull and bones or other comparable symbols or hieroglyphics"); *Campos v. Firestone Tire & Rubber Co.*, 485 A.2d 305, 310 (N.J. 1984) ("In view of the unskilled or semi-skilled nature of the work and the existence of many in the work force who do not read English, warnings in the form of symbols might have been appropriate."). *But see Thomas v. Clairol, Inc.*, 583 So. 2d 108, 110-11 (La. Ct. App. 1991) (rejecting claim by illiterates that written warning on hair dye product was inadequate).

physicians rarely see the actual product they have prescribed for any particular patient.<sup>273</sup> In particular, several courts have focused on the use of pharmaceutical company sales representatives to convey precautionary information about prescription drugs to physicians.<sup>274</sup> When companies do use their sales representatives to disseminate information about possible new side effects, some courts have criticized them for not sending a "Dear Doctor" letter instead.<sup>275</sup> Conversely, when "Dear Doctor" letters are circulated, the manufacturer may be held liable for not using sales representatives to convey the information.<sup>276</sup> Product labeling alone may, therefore, sometimes fail to satisfy the duty to warn. Just as in hindsight the content of warning statements may always seem inadequate, a manufacturer's choice of mechanisms for presenting these warnings may always appear to be less than perfect.

Thus, manufacturers may face liability either for not including in the label any mention of the particular injury suffered by a plaintiff, even if the risk of that injury is trivial, or for not conveying the warning with sufficient prominence on the label or through other means, even if the risk does not warrant such prominence relative to other possible consumer product hazards. Indeed, the use of federally-mandated warnings generally provides no safe harbor against tort claims. The next section discusses the extent to which federal regulatory requirements may displace the duty to warn under state common law.

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273. See, e.g., *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978, 992 (8th Cir. 1969) ("[I]t was not unreasonable to find that the appellant should have employed all its usual means of communication . . . to warn the prescribing physicians of these dangers."). Indeed, as two FDA officials once wrote, "corrective advertisements, 'Dear Doctor' letters, and the *FDA Drug Bulletin* . . . are presumably more effective in reaching practitioners than an additional warning added to the fine print of the product labeling." Peter H. Rheinstein & Carlene S. Baum, *Labeling Effectiveness and the Health Environment*, in *PRODUCT LABELING*, *supra* note 171, at 286. The FDA DRUG BULLETIN was renamed the FDA MEDICAL BULLETIN in 1991, and its scope expanded to include information about medical devices and other products.

274. See *Yarrow v. Sterling Drug, Inc.*, 263 F. Supp. 159, 163 (D.S.D. 1967), *aff'd*, 408 F.2d 978, 990 (8th Cir. 1969) (pharmaceutical company held liable for failure to warn of newly discovered side effects, notwithstanding letters it had sent to physicians, because it had not used its sales representatives to convey the information); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 663 (Cal. 1973); *Mahr v. G.D. Searle & Co.*, 390 N.E.2d 1214, 1232 (Ill. App. Ct. 1979); *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 987, 991-94 (8th Cir. 1969); *cf. Gracyalny v. Westinghouse Elec. Corp.*, 723 F.2d 1311, 1321 (7th Cir. 1983) (manufacturer of faulty circuit breakers may have been negligent in failing to follow up warning letter with personal visits by sales representatives); *Wallace v. Upjohn Co.*, 535 So. 2d 1110, 1117 (La. Ct. App. 1988) (sales persons would not be personally liable for failing to warn physicians), *cert. denied*, 539 So. 2d 630 (La. 1989).

275. See *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 84 (8th Cir. 1966); *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 146-47 (3d Cir. 1973) (noting that "some doctors did not take the time to speak to detail men, some did not always accept the product cards or brochures offered, and some did not always listen to what the detail men said about a drug").

276. *Yarrow*, 408 F.2d at 994 ("The trier of fact could reasonably conclude that the urgency of the circumstances reasonably required more than the relatively slow action and relative lack of emphasis employed in composing and circulating the 'Dear Doctor' letter.").

### C. *Federal Preemption*

In light of the competing labeling demands of federal regulators, state lawmakers, and the courts, manufacturers of consumer products have argued that federal law should preempt state law. The success of this argument has varied considerably, depending on the peculiar statutory provisions applicable to a category of products rather than the relative stringency of federal labeling requirements. The degree to which federal law displaces state statutory and regulatory requirements and the duties to warn under common law will be addressed in turn.

#### 1. *Preemption of State Requirements*

Under the Supremacy Clause of the United States Constitution,<sup>277</sup> federal law may supersede state law in a number of circumstances. First, Congress may by statute expressly preempt state law.<sup>278</sup> Second, in the absence of express statutory preemption, congressional intent to preempt state law sometimes may be inferred where a comprehensive scheme of federal regulation “left no room” for supplementation by state law.<sup>279</sup> Finally, even in the absence of implied preemption of an entire field of regulation, state law is preempted to the extent that it stands as an obstacle to the implementation of congressional objectives,<sup>280</sup> or actually conflicts with federal law.<sup>281</sup>

The most obvious case for preemption of state labeling requirements arises when Congress itself has specified what must be included in the labeling of consumer products. Congressional intent to preempt state law in such cases may be either express, as in the case of tobacco products and alcoholic beverages,<sup>282</sup> or implied, as in the case of coal tar hair dyes.<sup>283</sup>

Preemption is less certain when Congress delegates broad authority to administrative agencies to regulate consumer product labeling, unless an express preemption clause appears in the statute. The FD&C Act contains no general preemption provision.<sup>284</sup> Indeed, 1990 amendments to the Act, contained in the

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277. U.S. CONST. art. VI, cl. 2.

278. See *Jones v. Rath Packing Co.*, 430 U.S. 519, 530-32 (1977).

279. See *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

280. See *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

281. See *California Federal Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272, 281 (1987); *Ray v. Atlantic Richfield Co.*, 435 U.S. 151, 158 (1978); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963).

282. See 15 U.S.C. § 1334 (1988) (cigarettes); 15 U.S.C. § 4406(b) (1988) (smokeless tobacco products); 27 U.S.C.A. § 216 (West Supp. 1993) (alcoholic beverages).

283. See *Gorolin Corp. v. City of New York*, Food Drug Cosm. L. Rep. (CCH) ¶ 7116 (S.D.N.Y. 1949) (holding that the warning imposed by Congress for coal tar hair dyes preempted local labeling requirement).

284. See, e.g., *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 714-23 (1985) (FD&C Act did not preempt local ordinances concerning collection of blood); *Pharmaceutical Society of the State of New York v. Lefkowitz*, 586 F.2d 953, 958 & n.6 (2d Cir. 1978) (state requirement that

Nutrition Labeling and Education Act (NLEA), express an intent *not* to preempt state warning requirements applicable to food products.<sup>285</sup> This provision was "included to underscore that State laws requiring warnings pertaining to the safety of foods are not preempted."<sup>286</sup> On the other hand, state laws relating to medical devices *are* expressly preempted to the extent that FDA has imposed requirements relating to safety and effectiveness of particular devices.<sup>287</sup>

Other statutes governing the labeling of consumer products have broader preemptive effects. For instance, the FHSA expressly preempts state labeling requirements for hazardous substances.<sup>288</sup> FIFRA contains a preemption provision,<sup>289</sup> but it also includes a savings clause expressly permitting state regulation of pesticide sale and use,<sup>290</sup> leading courts to reach somewhat inconsistent decisions as to whether state warning requirements are preempted.<sup>291</sup> USDA

drug manufacturer be identified on the label not preempted); *Kellogg Co. v. Mattox*, 763 F. Supp. 1369, 1379 (N.D. Tex.) (state restrictions on health claims appearing on food labels not preempted), *aff'd mem.*, 940 F.2d 1530 (5th Cir. 1991).

285. Nutrition Labeling and Education Act, Pub. L. No. 101-535, § 6(c)(2), 104 Stat. 2364 (1990) (NLEA's express preemption provision "shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food."). The NLEA did not, however, reduce the preemptive effect of food labeling requirements under existing law, *id.* § 6(c)(3), and state requirements that actually conflict with FDA regulations have been held to be preempted. *See Grocery Mfrs. of America, Inc. v. Gerace*, 755 F.2d 993, 1001 (2d Cir.), *cert. denied*, 474 U.S. 820 (1985).

286. 136 CONG. REC. H5842 (daily ed. July 30, 1990) (statement of Mr. Waxman). Congressman Waxman, whose home state is California, added that "the most compelling argument for State regulation is where the States have adopted laws to protect the safety of their citizens." *Id.* at H5840. Absent peculiar local conditions affecting the hazardousness of foods, however, *see* 21 U.S.C.A. § 343-1(b)(3) (West Supp. 1993), the justification for state-by-state regulation of food labeling is weak. Senator Hatch, commenting on the need for uniform federal regulation of food labeling, countered that inconsistent state and local laws would "frustrate food safety and nutrition education efforts by presenting consumers with varying and inconsistent information and warnings." 136 CONG. REC. S16611 (daily ed. Oct. 24, 1990) (urging his colleagues to "remember that a warning on everything means a warning on nothing").

287. *See* 21 U.S.C. § 360k(a) (1988); 21 C.F.R. § 808.1 (1993); *Massachusetts v. Hayes*, 691 F.2d 57, 64 (1st Cir. 1982) (hearing aid requirements were preempted). Manufacturers of dental amalgam, threatened by citizen suits in California alleging a failure to warn of the presence of mercury, have sought a declaratory judgment that Proposition 65 is preempted under this provision. M-D-D-I REPORTS ("The Gray Sheet"), Oct. 4, 1993, at 19.

288. 15 U.S.C. § 1261 note (b)(1)(A) (1988) ("[N]o State or political subdivision of a State may establish or continue in effect a cautionary labeling requirement applicable to such [hazardous] substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling required under section 2(p) or 3(b)."); *Chemical Specialties Mfrs. Ass'n v. Clark*, 482 F.2d 325, 327-28 (5th Cir. 1973) (*per curiam*) (local ordinance requiring detergent labeling to list ingredients held expressly preempted). *But see Toy Mfrs. of America, Inc. v. Blumenthal*, 986 F.2d 615, 620-24 (2d Cir. 1992) (FHSA does not preempt Connecticut law requiring a warning of the risk to children under the age of three of choking on small parts of toys intended for use by older children); *Chemical Specialties Mfrs. Ass'n v. Allenby*, 958 F.2d 941, 949-50 (9th Cir.) (FHSA does not preempt Proposition 65 requirements), *cert. denied*, 113 S. Ct. 80 (1992).

289. 7 U.S.C. § 136v(b) (1988) ("[A] State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.").

290. *Id.* § 136v(a); *see also Wisconsin Public Intervenor v. Mortier*, 111 S. Ct. 2476, 2482-87 (1991); Comment, *Local Pesticide Regulation Since Wisconsin Public Intervenor v. Mortier*, 20 B.C. ENVTL. AFF. L. REV. 65 (1993).

291. *Compare New York State Pesticide Coalition, Inc. v. Jorling*, 874 F.2d 115, 119 (2d Cir. 1989) (state regulation requiring notice of pesticide application by posting signs is not preempted); *Allenby*, 958 F.2d at 949-50 (FIFRA does not preempt Proposition 65 requirements) *with Arkansas-Platte & Gulf*

labeling requirements enjoy broad federal preemption under the federal meat and poultry inspection acts.<sup>292</sup>

Even in the absence of express statutory preemption, however, an agency may issue regulations intended to preempt state labeling requirements.<sup>293</sup> Therefore, even if Congress were not prepared to revisit the issue in cases where an existing statute failed to contain a preemption clause, federal agencies could take the lead to ensure that their labeling requirements were not undermined by additional or different state warning requirements. FDA has done this in the case of three general OTC drug warnings,<sup>294</sup> as have other agencies on certain occasions.<sup>295</sup> Sometimes agency labeling requirements will be held to preempt by implication inconsistent state laws,<sup>296</sup> and agencies also can preempt state requirements for product risks that they have decided do not merit cautionary labeling.<sup>297</sup>

Proposition 65 has raised a number of difficult preemption issues. The law itself recognizes that it cannot apply to “[a]n exposure for which federal law governs warning in a manner that preempts state authority.”<sup>298</sup> USDA has taken the position that the meat and poultry inspection acts expressly preempt Proposition 65 product warning requirements, and the Agency rejected one manufacturer’s proposed label because it regarded the California cancer warning

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Partnership v. Van Waters & Rogers, Inc., 981 F.2d 1177, 1179 (10th Cir.) (finding express preemption of failure-to-warn claims), *cert. denied*, 114 S. Ct. 60 (1993).

292. 21 U.S.C. § 678 (1988) (meat labeling “requirements . . . in addition to, or different than, those made under this chapter may not be imposed by any State”); *id.* § 467e (same provision applicable to poultry products); *see also* Jones v. Rath Packing Co., 430 U.S. 519, 530-32 (1977) (California net weight labeling requirements are expressly preempted by these provisions); Armour & Co. v. Ball, 468 F.2d 76, 84-85 (6th Cir. 1972) (Michigan ingredient requirements preempted), *cert. denied*, 411 U.S. 981 (1973); Meat Trade Inst., Inc. v. McLaughlin, 326 N.Y.S.2d 683, 684 (N.Y. App. Div. 1971) (*per curiam*).

293. *See* City of New York v. FCC, 486 U.S. 57, 64 (1988); Capital Cities Cable, Inc. v. Crisp, 467 U.S. 691, 699-700 (1984); Fidelity Federal Sav. & Loan Ass’n v. de la Cuesta, 458 U.S. 141, 154, 167 (1982); 59 Fed. Reg. 3944, 3948-49 (1994) (FDA proposal to preempt state disclosure laws). *See generally* Richard J. Pierce, Jr., *Regulation, Deregulation, Federalism, and Administrative Law: Agency Power to Preempt State Regulation*, 46 U. PITT. L. REV. 607 (1985); Paula A. Sinozich et al., Project, *The Role of Preemption in Administrative Law*, 45 ADMIN. L. REV. 107 (1993). Such administrative preemption would, of course, not be possible if it conflicted with contrary Congressional intent.

294. *See* 51 Fed. Reg. 8180, 8181 (1986) (Reye syndrome warning); 47 Fed. Reg. 54,750, 54,756 (1982) (general pregnancy warning for OTC drug products); 47 Fed. Reg. 50,442, 50,447-48 (1982) (tamper-resistant packaging and associated labeling requirements).

295. *See, e.g.*, 52 Fed. Reg. 34,698, 34,702 (1987) (CPSC warning requirement for products containing methylene chloride).

296. *See* Cosmetic, Toiletry & Fragrance Ass’n v. Minnesota, 440 F. Supp. 1216, 1219, 1225 (D. Minn. 1977) (granting preliminary injunction against enforcement of Minnesota’s CFC labeling requirement which was held to be preempted by FDA’s regulation), *aff’d*, 575 F.2d 1256 (8th Cir. 1978) (*per curiam*).

297. *See* Capital Cities Cable, Inc. v. Crisp, 467 U.S. 691, 708 (1984) (state not permitted to exercise police powers where the Agency determined that restrictions were not in the public interest); Ray v. Atlantic Richfield Co., 435 U.S. 151, 178 (1978) (state not permitted to act where federal officials’ failure to do so amounts to a ruling that regulation is inappropriate); Bethlehem Steel Co. v. New York State Labor Relations Bd., 330 U.S. 767, 774 (1947); *cf.* Toy Mfrs. of America, Inc. v. Blumenthal, 986 F.2d 615, 621-23 (2d Cir. 1992) (CPSC’s failure to adopt warning requirements for toys containing small parts did not reflect any intent to foreclose state action). *See generally* Note, “Phony” Intent?: An Examination of Regulatory-Preemption Jurisprudence, 67 N.Y.U. L. REV. 108 (1992).

298. CAL. HEALTH & SAFETY CODE § 25249.10(a) (1992).

as misleading.<sup>299</sup> In addition, although BATF has not taken a position on the matter, the California warning for alcoholic beverages generally duplicates the requirement imposed by Congress in 1988.<sup>300</sup> Likewise, the carcinogenic properties of tobacco products would trigger Proposition 65's warning requirements were it not for the express preemption clauses in the applicable federal statutes.<sup>301</sup> Even so, the broad array of options available for communicating a warning under Proposition 65 means that federal labeling requirements will rarely preempt the California requirements entirely.<sup>302</sup>

In short, the scope of federal preemption will depend on both the clarity of the preemptive intent expressed by Congress or an agency and the nature of the state's warning requirements. If state lawmakers are able to evade all but the most far-reaching statements of preemptive intent by allowing risk information to be provided by methods other than labeling, they may succeed in continuing to undermine carefully balanced federal warning efforts.<sup>303</sup> The irony, of course, is that manufacturers attempting to comply with state warning requirements by means other than product labeling may face claims that they failed to choose the most effective way to convey the risk information.<sup>304</sup>

## 2. Preemption of State Tort Claims

The threat of inconsistency in product labeling is greatly compounded when courts allow juries to impose additional demands for warning statements. Courts have largely ignored the relevance of warnings required by legislatures and administrative agencies, refusing to accord preemptive effect to federal requirements. Even specific warnings mandated by Congress will not

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299. Letter from Margaret O'K. Glavin, Director, Standards and Labeling Division, Food Safety and Inspection Service, USDA, to William J. Coffin, American Home Food Products, Inc. (Nov. 20, 1987) (on file with the author). Unlike FDA's regulation of food product labeling, USDA preapproves the labeling of specific meat products. 9 C.F.R. § 317.4(a) (1993).

300. See *supra* notes 49-55 and accompanying text. Both describe the risk of birth defects, and, although it does not use the word "cancer," the federal warning mentions other "health problems."

301. See *supra* note 282; John R. Emshwiller, *Vons Stores Remove Tobacco Products That Lack Health-Warning Labels*, WALL ST. J., Oct. 5, 1988, at B6 (describing the treatment of various tobacco products in California). Of course the federal warning statements describing the risk of lung or mouth cancer should satisfy a manufacturer's duty under state law, but the system of rotation for the federal warnings means that a majority of tobacco products sold in any one year will not include a cancer warning in their labeling; see also *supra* note 287 (raising question of preemption in the case of dental amalgam, a product regulated by FDA as a medical device).

302. See *D-Con Co. v. Allenby*, 728 F. Supp. 605, 607 (N.D. Cal. 1989); *Chemical Specialties Mfrs. Ass'n v. Allenby*, 744 F. Supp. 934, 935-36 (N.D. Cal. 1990), *aff'd*, 958 F.2d 941, 947-48 (9th Cir.), *cert. denied*, 113 S. Ct. 80 (1992). But cf. *King v. E.I. du Pont de Nemours & Co.*, 806 F. Supp. 1030, 1037 n.4 (D. Me. 1992) (preemption of failure-to-warn claims under FIFRA extended to include mechanisms in addition to EPA-approved product labels), *aff'd*, 996 F.2d 1346 (1st Cir. 1993).

303. But see Susan B. Foote, *Administrative Preemption: An Experiment in Regulatory Federalism*, 70 VA. L. REV. 1429, 1463 (1984) (recommending that agencies leave states free to impose more stringent labeling or other requirements).

304. See *supra* note 232.

necessarily preempt failure-to-warn claims.<sup>305</sup> The Supreme Court recently addressed the question of whether the Federal Cigarette Labeling and Advertising Act preempted common law tort claims.<sup>306</sup> Since 1965, Congress has prescribed the warnings that must appear on cigarette labels.<sup>307</sup> Section 5(b) of the Act, as amended in 1969, provided that:

No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the package of which are labeled in conformity with the provisions of this chapter.<sup>308</sup>

The Justices divided three ways, issuing a plurality decision. A majority of the Justices agreed that the Act, as amended in 1969, expressly preempts products liability actions grounded on failure-to-warn (but not other) claims, even though the statute did not specifically delineate such claims as subject to preemption.<sup>309</sup> Application of the Court's decision to other labeling statutes has been somewhat haphazard to date.<sup>310</sup>

The preemptive force of specific agency warning requirements depends on how clearly the statute or regulation expresses the intent to displace common law claims. As explained above, state requirements governing the safety or effectiveness of FDA-regulated medical devices were expressly preempted by Congress.<sup>311</sup> Several courts have held that this provision of the FD&C Act also preempts common law tort claims to the extent that FDA governs the labeling of a device. For instance, claims against tampon manufacturers for failure to warn of toxic shock syndrome have been dismissed because the Agency has

305. See, e.g., *D'Arienzo v. Clairol, Inc.*, 310 A.2d 106, 109 (N.J. Super. 1973) (statutory coal tar hair dye warning would not bar failure-to-warn claim brought by an individual who suffered an allergic reaction).

306. *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992) (plurality).

307. See *supra* notes 32-42 and accompanying text.

308. 15 U.S.C. § 1334(b) (1988). The Court held that the 1965 version, which provided that "[n]o statement relating to smoking and health" shall be required in the labeling or advertising of cigarettes labeled in conformity with the Act, did not preempt common law tort actions. 112 S. Ct. at 2619. This provision should be contrasted with the preemption provisions in the Comprehensive Smokeless Tobacco Health Education Act of 1986, discussed in *supra* notes 43-47 and accompanying text. State and local statutes or regulations requiring a statement relating to the use of smokeless tobacco products and health are preempted, but common law liability is expressly not affected. 15 U.S.C. § 4406(b), (c) (1988).

309. See 112 S. Ct. at 2619-24 (Stevens, J., joined by Rehnquist, C.J., White and O'Connor, JJ.) (concluding that breach of express warranty and certain fraudulent misrepresentation claims were not preempted). Two other Justices found an even broader preemptive effect in the statute and would have held all common law claims preempted under the 1969 amendment. See *id.* at 2632-38 (Scalia, J., joined by Thomas, J.). The remaining three Justices would have held none of the claims preempted. See *id.* at 2625-31 (Blackmun, J., joined by Kennedy and Souter, JJ.). See generally Richard C. Ausness, *The Impact of the Cipollone Case on Federal Preemption Law*, 15 J. PROD. & TOXICS LIAB. 1 (1993).

310. See, e.g., *King v. Collagen Corp.*, 983 F.2d 1130, 1133-36 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993); *Davidson v. Velsicol Chemical Corp.*, 834 P.2d 931, 933 n.2 (Nev. 1992) (*per curiam*), *cert. denied*, 113 S. Ct. 1944 (1993); Case Note, *Preemption Doctrine After Cipollone*, 106 HARV. L. REV. 963 (1993).

311. See *supra* note 287.

issued specific warning requirements for these products.<sup>312</sup> Recent preemption decisions involving prescription medical devices are even more sweeping, holding that premarket approval by FDA defeats a variety of common law claims including those alleging defective design, testing, manufacture, or labeling.<sup>313</sup>

In sharp contrast, courts have universally rejected the argument that FDA regulations generally preempt state tort law for prescription drugs.<sup>314</sup> Although they are regulated somewhat more stringently than medical devices, prescription drugs are not covered by a comparable express preemption provision. Thus, common law failure-to-warn claims are routinely brought against pharmaceutical manufacturers even though drugs are subject to the most detailed and carefully applied labeling requirements imposed by the federal government.

The primary rationale for ignoring FDA's drug labeling decisions is that the Agency has imposed only "minimum" standards open to supplementation by a lay jury's verdict enforcing a manufacturer's common law duty to warn.<sup>315</sup> As one former FDA Chief Counsel commented a few years ago, however, "FDA surely does not regard its own prescription drug labeling decisions as merely establishing a floor."<sup>316</sup> Another common refrain is that state common law merely supplements FDA regulation by creating a compensatory mechanism

312. See *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246-47 (5th Cir. 1989); *Bejarano v. International Playtex, Inc.*, 750 F. Supp. 443, 445-46 (D. Idaho 1990); *Berger v. Personal Products, Inc.*, 797 P.2d 1148, 1150-51 n.9 (Wash. 1990) (collecting cases), *cert. denied*, 111 S. Ct. 1584 (1991). The regulation is discussed in *supra* note 133. Preemption in these cases means that failure-to-warn claims can only be premised on a failure to provide the warning mandated by federal regulation and not on some general state common law standard of adequacy. See, e.g., *Stewart v. International Playtex, Inc.*, 672 F. Supp. 907, 910 (D.S.C. 1987) ("The remedy is available to plaintiff, but compliance with federal law protects the defendant from the vagaries of each state's judicial system."); *Poloney v. Tambrands, Inc.*, 399 S.E.2d 208, 210 (Ga. 1991).

313. See *King*, 983 F.2d at 1133-36 (injectable collagen); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421-25 (5th Cir. 1993) (same), *cert. denied*, 114 S. Ct. 86 (1993); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1333 (7th Cir.) (investigational intraocular lenses), *cert. denied*, 113 S. Ct. 327 (1992); *Lars Noah, Amplification of Federal Preemption in Medical Device Cases*, 49 FOOD & DRUG L.J. \_\_ (forthcoming 1994).

314. See *Hurley v. Lederle Laboratories*, 863 F.2d 1173, 1176 n.2 (5th Cir. 1988) (citing 14 federal district court and three state court decisions involving vaccines that rejected preemption defense); *Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1112 n.1 (4th Cir.) (citing nine federal district court decisions involving vaccines and rejecting preemption defense), *cert. denied*, 488 U.S. 908 (1988).

315. *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741, 746 (11th Cir.) ("An FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes."), *cert. denied*, 479 U.S. 950 (1986); *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 931 (Kan. 1990); *Feldman v. Lederle Laboratories*, 479 A.2d 374, 391 (N.J. 1984); RESTATEMENT (SECOND) OF TORTS § 288C(1965) ("Compliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions."); *Henderson & Twerski, supra* note 240, at 320 ("[F]or reasons that we find difficult to understand, courts have not deferred to the determinations of product safety agencies . . . . The analysis usually begins and ends with the statement that agency standards are minimum, not maximum, standards and that courts are therefore free to disregard them.")

316. *Scarlett, supra* note 163, at 40. "On the contrary, the FDA regards such labeling as fully adequate for the purpose of informing physicians of all necessary information." *Id.*



not available under federal law.<sup>317</sup> In several cases, for instance, courts have allowed juries to find that the specific warnings provided to patients by manufacturers of oral contraceptives were inadequate even though the labeling fully complied with FDA's PPI regulation.<sup>318</sup> Ironically, even an apparent refusal by FDA to allow the addition of a warning may not protect a manufacturer from tort liability for failing to include precisely that warning.<sup>319</sup>

In one widely reported jury verdict, a drug company was held liable for failing to warn of the risks of blindness associated with the accidental intraocular injection of a corticosteroid. Although not approved by FDA to treat inflammations of the eye, this drug was widely used by the ophthalmological community for that purpose. The jury returned a verdict against the manufacturer for \$3 million in compensatory damages and \$124.5 million in punitive damages.<sup>320</sup> The trial judge remitted the punitive damage award to \$35 million but otherwise left the jury's verdict undisturbed. Furthermore, he excluded as irrelevant evidence that the company had been unable to convince FDA to include the precise warning urged by the plaintiff.<sup>321</sup> The judge rejected the manufacturer's argument that evidence of unsuccessful attempts to persuade FDA of the need for an additional warning should at least be permitted for purposes of rebutting allegations of negligent failure-to-warn.<sup>322</sup>

Even though they have rejected preemption defenses, most courts recognize that FDA-approved labeling provides some evidence of what constitutes an adequate warning.<sup>323</sup> Some state statutes also create a rebuttable presumption

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317. *E.g.*, *Mazur v. Merck & Co.*, 742 F. Supp. 239, 247 (E.D. Pa. 1990); *Feldman v. Lederle Laboratories*, 592 A.2d 1176, 1192 (N.J. 1991), *cert. denied*, 112 S. Ct. 3027 (1992).

318. *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 658 (1st Cir. 1981); *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 70-71 (Mass.), *cert. denied*, 474 U.S. 920 (1985); *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 534 (Or. 1974).

319. *See Wooderson v. Ortho Pharmaceutical Corp.*, 681 P.2d 1038, 1057 (Kan.) (ignoring FDA letter to manufacturer rejecting addition of requested warning), *cert. denied*, 469 U.S. 965, (1984); *Feldman*, 479 A.2d at 378-79; Charles J. Walsh & Marc S. Klein, *The Conflicting Objectives of Federal and State Tort Law Drug Regulation*, 41 FOOD DRUG COSM. L.J. 171, 185-88 (1986); Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 779 (1990).

320. 19 Prod. Safety & Liab. Rep. (BNA) 1169 (1991) (describing *Proctor v. Upjohn Co.*). The decision is currently on appeal.

321. *Id.*; *see also May v. Parke, Davis & Co.*, 370 N.W.2d 371, 380 (Mich. Ct. App. 1985) (excluding evidence that FDA had subsequently rejected another manufacturer's identical proposed warning as unsubstantiated). Upjohn prevailed in a case involving a different off-label use. *Hahn v. Richter*, 628 A.2d 860 (Pa. Super. Ct. 1993). During trial, Upjohn had presented testimony from Herbert Ley, a former FDA Commissioner, explaining that the Agency "would not have allowed Upjohn to contact physicians or send a 'Dear Doctor' letter regarding the intrathecal use of Depo-Medrol because it was not an approved use for the drug." *Id.* at 863.

322. 19 Prod. Safety & Liab. Rep. (BNA) 1169 (1991). On remand, the appellate court in *Feldman* held open the question of "whether the correspondence from the FDA was sufficient evidence to justify Lederle's decision to withhold a warning until such time as the FDA was convinced otherwise." *Feldman v. Lederle Laboratories*, 608 A.2d 356, 359 (N.J. Super. Ct. App. Div.), *aff'd in part*, 625 A.2d 1066, 1070 (N.J. 1993).

323. *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) ("In North Carolina, as elsewhere, compliance with federal laws and regulations concerning a drug, though pertinent, does not in itself absolve a manufacturer of liability."); *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 70-

that a drug warning is adequate if approved by FDA,<sup>324</sup> and other states recognize more general defenses for any products whose labeling is regulated by the federal government.<sup>325</sup> A few courts have even registered a willingness to consider a limited "preemption" defense to failure-to-warn claims if FDA was provided with all relevant information at the time it approved labeling for the new drug,<sup>326</sup> but this is clearly a minority position.<sup>327</sup> On the other hand, any failure to abide by FDA requirements such as those for the reporting of adverse drug experiences may constitute negligence per se.<sup>328</sup>

In support of the general refrain that federal regulations represent only minimum safety requirements open to supplementation by juries, courts have emphasized that additional or more forceful warnings may be added to labeling without prior FDA approval.<sup>329</sup> FDA pronouncements on the subject have contributed to the confusion. The Agency has on a number of occasions expressed its intent to stay above the products liability fray.<sup>330</sup> In the preamble to its drug labeling regulations, in fact, FDA emphasized that manufacturers may add warnings without prior approval.<sup>331</sup> Although these options for

71 (Mass.) ("compliance with FDA [warning] requirements, though admissible to demonstrate lack of negligence, is not conclusive"), *cert. denied*, 474 U.S. 920 (1985).

324. *E.g.*, N.J. STAT. ANN. § 2A:58C-4 (West 1993); OHIO REV. CODE ANN. § 2307.76(C) (Baldwin 1994).

325. TENN. CODE ANN. § 29-28-104 (1993); *see also* Goins v. Clorox Co., 926 F.2d 559, 561-62 (6th Cir. 1991) (applying Tennessee statute where product labels complied with FIFRA and FHSA); Uptain v. Huntington Lab, Inc., 685 P.2d 218, 222 (Colo. Ct. App. 1984) (applying similar Colorado statute to label approved by EPA), *aff'd*, 723 P.2d 1322 (Colo. 1986).

326. Hurley v. Lederle Laboratories, 863 F.2d 1173, 1179 (5th Cir. 1988); McDaniel v. McNeil Lab., Inc., 241 N.W.2d 822, 828 (Neb. 1976); *cf.* Ramirez v. Plough, Inc., 25 Cal. Rptr. 2d 97, 102 (Cal. 1993) ("[T]here is some room in tort law for a defense of statutory compliance.").

327. Abbot v. American Cyanamid Co., 844 F.2d 1108, 1112 (4th Cir.) (rejecting preemption defense even while acknowledging that "[t]he language of the label is subject to FDA approval, and once approved, cannot be changed without FDA approval"), *cert. denied*, 488 U.S. 908 (1988); Tarallo v. Searle Pharmaceutical, Inc., 704 F. Supp. 653, 660 (D.S.C. 1988) (refusing to follow what it called dicta in *Hurley* concerning implied specific preemption).

328. Stanton v. Astra Pharmaceutical Prod., Inc., 718 F.2d 553, 565 (3d Cir. 1983); Orthopedic Equipment Co. v. Eutsler, 276 F.2d 455, 461 (4th Cir. 1960); Lukaszewicz v. Ortho Pharmaceutical Corp., 510 F. Supp. 961, 964-65 (E.D. Wis. 1981); Allen v. Delchamps, Inc., 624 So. 2d 1065, 1067 (Ala. 1993); Toole v. Richardson-Merrell, Inc., 60 Cal. Rptr. 398, 409 (Cal. Ct. App. 1967).

329. *E.g.*, Feldman v. Lederle Laboratories, 479 A.2d 374, 390 (N.J. 1984); *cf.* Osburn v. Anchor Lab., 825 F.2d 908, 912 & n.4 (5th Cir. 1987) (relying on parallel provisions for warnings on animal drugs), *cert. denied*, 485 U.S. 1009 (1988); *In re* Tetracycline Cases, 747 F. Supp. 543, 549-50 (W.D. Mo. 1989) (pointing out that warnings on antibiotics may be added to the label in advance of FDA approval and that there are other means for disseminating warning information which would not conflict with federal requirements).

330. *See* 59 Fed. Reg. 3944, 3948 (1994) (to be codified at 21 C.F.R. § 20.63(f)) ("FDA recognizes that product liability plays an important role in consumer protection."); 44 Fed. Reg. 37,434, 37,447 (1979) (citing *McEwen* without criticism); 43 Fed. Reg. 4214, 4214-15 (1978) (revised PPI for oral contraceptives); 42 Fed. Reg. 37,636, 37,637 (1977) ("[W]hether particular labeling [i.e., the estrogen PPI] may alter a manufacturer's liability in a given instance cannot be considered as a dispositive factor by the Commissioner").

331. "[T]hese labeling regulations do not prohibit a manufacturer, packer, relabeler, or distributor from warning health care professionals whenever possibly harmful adverse effects associated with the use of the drug are discovered." 44 Fed. Reg. 37,434, 37,447 (1979) ("The addition to labeling and advertising of additional warnings, as well as contraindications, adverse reactions, and precautions regarding the drug, or

conveying additional risk information are not prohibited, their availability is significantly restricted by FDA. Moreover, the Agency's apparent lack of opposition to second-guessing by the courts is difficult to fathom, though one commentator has suggested that agencies like FDA may not mind having the tort system serve as a "safety valve" for deflecting adverse publicity from themselves when hazards associated with an approved product later come to light.<sup>332</sup>

Although in theory drug manufacturers are free to add warnings in advance of FDA approval,<sup>333</sup> they may not enjoy any real flexibility to alter previously approved labeling. As one former FDA Chief Counsel explained, "the actual freedom of manufacturers unilaterally to change the package insert is minimal."<sup>334</sup> Moreover, even when a manufacturer may add a warning in advance of receiving Agency approval, the additional warning may not be used if, after reviewing the supplement, FDA rejects the modified language. "Although the FDA is not rigidly opposed to adding more precautionary information to labeling, it is conscious of the problem of information overload . . . [and it] would not acquiesce in defensive labeling that lacked medical support."<sup>335</sup> The possibility of Agency disapproval means that manufacturers typically await at least informal pre-approval before changing product labeling. In the interim, however, companies may be held liable if they have not at least requested FDA approval of an additional warning as soon as a new hazard is discovered.<sup>336</sup>

Even while conceding that prescription drug labeling is subject to strict FDA regulation that prohibits warnings about unsubstantiated risks, some courts have taken the position that warnings could still be conveyed by means not

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the issuance of letters directed to health care professionals (e.g., 'Dear Doctor' letters containing such information) is not prohibited by these regulations.").

332. Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 334 (1985).

333. 21 C.F.R. § 314.70(c)(2)(i) (1993); 44 Fed. Reg. 37,434, 37,447 (1979) (explaining that this regulation "permits the addition to the drug's labeling or advertising of information about a hazard without advance approval of the supplemental application by FDA"). Until 1965, FDA regulations applicable to drugs prohibited companies from adding warnings or other information without prior approval. See 25 Fed. Reg. 12,592, 12,595 (1960). These regulations were amended in 1965, allowing labeling changes related to safety to be "placed into effect at the earliest possible time." 30 Fed. Reg. 993 (1965) (goal was "to enable prompt adoption of such changes").

334. Richard M. Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 FOOD DRUG COSM. L.J. 233, 236 (1986); see also Scarlett, *supra* note 163, at 36, 40. Manufacturers of approved Class III devices only have limited flexibility to alter warnings without clearance from the agency. 21 C.F.R. § 814.39(d) (1993); see also Lindquist v. Tambrands, Inc., 721 F. Supp. 1058, 1060 (D. Minn. 1989). Revisions to risk information in labeling can be implemented only after FDA has acknowledged that the submission is being processed as a special supplement. ODE Guidance Memorandum P90-1 (Apr. 16, 1990) (on file with the author).

335. Scarlett, *supra* note 163, at 40.

336. *In re Tetracycline Cases*, 747 F. Supp. 543, 550 (W.D. Mo. 1989); cf. *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978, 991-92 (8th Cir. 1969); *Miller v. Upjohn Co.*, 465 So. 2d 42, 45 (La. Ct. App.) (jury "could reasonably have found that Upjohn was tardy in applying for the warning label"), *cert. denied*, 467 So. 2d 533 (La. 1985).

subject to federal control.<sup>337</sup> These courts fail to recognize, however, that other avenues of communication cannot be used to circumvent FDA decisions about appropriate labeling. "Dear Doctor" letters, for instance, are subject to specific FDA regulations<sup>338</sup> and would have to abide by the same restrictions that apply to the content of package inserts.<sup>339</sup> The Agency restricts the use of "Dear Doctor" letters because it wants to reserve them to alert physicians to critical new information. If courts force manufacturers to inundate doctors with such letters, these communications might then be ignored along with much of the other mail routinely sent to physicians' offices.<sup>340</sup> Nonetheless, courts have generally failed to appreciate these important limitations.<sup>341</sup>

Courts should give labeling decisions made by expert federal agencies more respect. FDA strictly controls the labeling of prescription medications, demanding that cautionary information appear in appropriate categories and prohibiting the inclusion of unsubstantiated warnings. Yet judges and juries have shown little compunction about second-guessing these and other FDA labeling determinations. Courts are divided over whether common law claims are preempted under other labeling statutes such as FHSA<sup>342</sup> and FIFRA.<sup>343</sup>

337. See, e.g., *In re Tetracycline Cases*, 747 F. Supp. at 549; *Herr v. Carolina Log Buildings, Inc.*, 771 F. Supp. 958, 961 (S.D. Ind. 1989) (describing various alternatives for conveying risk information about pesticides); *Baker v. St. Agnes Hosp.*, 421 N.Y.S.2d 81, 86 (N.Y. App. Div. 1979) ("There are other, well-known methods by which pharmaceutical manufacturers apprise the medical profession of the dangers of a drug."); *Finn v. G.D. Searle & Co.*, 677 P.2d 1147, 1169 n.20, (Cal. 1984) (Bird, C.J., dissenting) ("These include advertising and promotional literature, letters to the medical profession and oral communications by sales representatives.").

338. See 21 C.F.R. § 200.5 (1993) (Because "such mail should be distinctive in appearance so that it will promptly be recognized and read," FDA requests that drug manufacturers adhere to certain guidelines for the notice on the envelope and that they not "use the distinctive envelope for ordinary mail"). Thus, if the information in the letter "concerns a significant hazard to health," the outside of the envelope should carry the following boxed statement in large red lettering: "IMPORTANT DRUG WARNING." *Id.* § 200.5(c)(1). Other significant labeling changes should be noted with the following boxed statement in large blue lettering: "IMPORTANT PRESCRIBING INFORMATION." *Id.* § 200.5(c)(2).

339. See *id.* §§ 201.56, 202.1(f)(2); *Cooper, supra* note 334, at 240 ("FDA commonly reviews 'Dear Doctor' letters and similar communication in advance."). Nor can these limitations be escaped by instructing sales representatives to communicate verbal warnings not yet approved by FDA, especially if they might imply an unapproved use. See *Hahn v. Richter*, 628 A.2d 860, 863 (Pa. Super. Ct. 1993); 21 C.F.R. § 201.56(c) (1993) ("No implied claims or suggestions of drug use may be made [in drug labeling] if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness."); 37 Fed. Reg. 16,503, 16,504 (1972); Lars Noah, *Death of a Salesman: To What Extent Can the FDA Regulate the Promotional Statements of Pharmaceutical Sales Representatives?*, 47 FOOD & DRUG L.J. 309, 320-22 (1992); Philip J. Hilts, *Court Bans Impropriety in Promoting a Drug*, N.Y. TIMES, Aug. 3, 1993, at C5 (describing recent FDA consent decree prohibiting promotion of drug by company sales representatives for unapproved uses).

340. See *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 146 (3d Cir. 1973) ("Nor was mailing drug literature to physicians necessarily an effective way to reach them. . . . [T]he jury could reasonably have found that a considerable amount of such literature winds up in the wastebasket and is not adequate to advise doctors concerning matters of utmost importance.").

341. See *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 84 (8th Cir. 1966) (ignoring manufacturer's argument that the Dear Doctor "letter was not sent sooner because the connection between the drug and the condition was not yet sufficiently established, and because some time was consumed in clearing the letter with the FDA").

342. Compare *Burch v. Amsterdam Corp.*, 366 A.2d 1079, 1086 (D.C. App. 1976) (no preemption of claim involving adhesive product) with *Lee v. Boyle-Midway Household Products, Inc.*, 792 F. Supp. 1001, 1008-09 (W.D. Pa. 1992) (finding failure-to-warn claim involving a drain cleaner product impliedly

Even if they are not willing to find common law failure-to-warn claims preempted by federal requirements, however, “courts must acknowledge their own inability to grasp the totality of warnings problems by deferring more readily to other decisionmakers who do possess the institutional capability to assess warnings as a whole.”<sup>344</sup> As is discussed at length in Part V, the refusal to do so has resulted in the counterproductive proliferation of warnings about insignificant or unsubstantiated risks in the labeling of consumer products.

#### IV. Considerations in Designing Warning Labels

Unless used in a consistent and thoughtful manner, warning statements will fail to fulfill their intended purposes. The various shortcomings of current labeling requirements suggest a number of important lessons. As explained in the sections that follow, it is essential that warning statements be introduced with appropriate signal words, specify the nature of the hazard, be comprehensible to consumers, describe the degree of uncertainty underlying the risk estimate, and explain how to avoid the risk. Although these goals require certain trade-offs and may at times conflict, especially when attempts are made to convey ambiguous risk information in a way that is both accurate and understandable, they represent important considerations for those who design or evaluate warnings. In addition, by testing the effectiveness of warning efforts rather than simply relying on intuitive and unverified judgments about their utility, decisionmakers could acquire a better basis for designing or revising hazard statements in product labeling.

One of the earliest risk labeling systems, a voluntary standard published by the Manufacturing Chemists Association (MCA) in the 1940s, incorporated many important considerations relevant in the design of precautionary labeling, including the consistent use of different signal words, uniform formats, simple

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preempted).

343. *Compare* *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1539-42 (D.C. Cir. (no preemption), *cert. denied*, 469 U.S. 1062 (1984); *and* *Couture v. Dow Chemical U.S.A.*, 804 F. Supp. 1298, 1302 (D. Mont. 1992) (same) *with* *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 369-71 (7th Cir. 1993) (FIFRA preempts common law failure-to-warn claim against the manufacturer of a bathroom cleaner); *Papas v. Upjohn Co.*, 985 F.2d 516, 518-20 (11th Cir.) (per curiam) (finding express preemption of common law failure-to-warn claims under FIFRA, after remand from the Supreme Court for further consideration in light of its decision in *Cipollone*), *cert. denied*, 114 S. Ct. 300 (1993); *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers Inc.*, 981 F.2d 1177, 1179 (10th Cir.) (same), *cert. denied*, 114 S. Ct. 60 (1993); *and* *Davidson v. Velsicol Chemical Corp.*, 834 P.2d 931, 936-37 (Nev. 1992) (per curiam) (finding implied preemption of failure-to-warn claims under FIFRA), *cert. denied*, 113 S. Ct. 1944 (1993). *See generally* R. David Allnut, Comment, *FIFRA Preemption of State Common Law Claims After Cipollone v. Liggett Group, Inc.*, 68 WASH. L. REV. 859, 869-76 (1993) (criticizing recent decisions finding express preemption of common law claims under FIFRA).

344. *Henderson & Twerski*, *supra* note 240, at 321 (adding that agencies “possess not only expertise but also a capacity for knowledge and memory which courts cannot match”); *see also* Lars Noah, *The Dysfunctions of Drug Review in the Courts*, 5 REG. AFF. 387, 401 (1993). *See generally* Michael D. Green, *When Toxic Worlds Collide: Regulatory and Common Law Prescriptions for Risk Communication*, 13 HARV. ENV. L. REV. 209 (1989).

language, presentation of precautionary instructions in tandem with identification of the hazard, and use of warnings only when necessary.<sup>345</sup> Although features of the MCA system were incorporated in the original Federal Hazardous Substances Labeling Act of 1960,<sup>346</sup> as well as in EPA's pesticide labeling regulations,<sup>347</sup> the lessons reflected in these efforts have been lost on some of the persons now responsible for designing or reviewing consumer product warning labels.

#### A. *Selecting Appropriate Signal Words*

Careful choice of introductory signal words (such as "Danger," "Warning," "Alert," and "Caution") is important. All of the cautionary statements mandated by Congress, with the exception of those for coal tar hair dyes and saccharin, are designated as "Warnings," and sometimes accompanied by a reference to the "Government" or the "Surgeon General." As discussed in Part II of this Article, agency practice with regard to choice of signal words is varied and sometimes inconsistent. EPA's pesticide labeling regulations create a strict hierarchy for the use of signal words depending on the risk of acute toxicity.<sup>348</sup> CPSC's labeling regulations governing hazardous substances parallel EPA's pesticide requirements in some respects, but the CPSC allows the terms "Warning" and "Caution" to be used interchangeably.<sup>349</sup> FDA's prescription drug and medical device labeling regulations, which take both acute and chronic health hazards into account, use a similar hierarchy (ranging from "Contraindications" to "Precautions") depending on the seriousness of the risk.<sup>350</sup> FDA warning requirements with respect to OTC drugs, food products, and cosmetics are less discriminating in choice of signal words, frequently treating "Warning" and "Caution" as synonyms.<sup>351</sup> For their part, state lawmakers and courts appear inclined to designate all hazard information as a "Warning."

Introducing a hazard statement as a "Warning" often is unjustified. Research confirms that, to maximize the effectiveness of precautionary information, signal words should be consistent with the degree of risk reflected

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345. George T. Scriba, *The Federal Hazardous Substances Labeling Act*, 16 FOOD DRUG COSM. L.J. 615, 628-31 (1961) (describing the MCA manual and its substantial influence on what is now the FHSA). The MCA system is the basis for the system adopted by the American National Standards Institute (ANSI). ANSI Standard Z 129.1 (1988), discussed in Betso, *supra* note 202, at 219-20.

346. See *supra* notes 11-13 and accompanying text.

347. See *supra* notes 185-201 and accompanying text.

348. 40 C.F.R. § 156.10(h)(1)(i)(E) (1993).

349. 16 C.F.R. §§ 1500.3(a)(14)(i)(D), 1500.130(b) (1993).

350. See *supra* notes 146-163, and 179, and accompanying text.

351. In discussing OTC drug labeling, the Agency admitted that "historically there has not been consistent usage of the signal words 'warning' and 'caution' . . . ." 57 Fed. Reg. 58,356, 58,367 (1992). Tampon labels use the signal word "Alert" to introduce risk information about toxic shock syndrome (TSS). See *supra* note 133.

in the text of the statement.<sup>352</sup> The word “Warning” sounds a note of urgency, designed to draw consumer attention to the information conveyed and typically also to encourage some modification of behavior. Thus, in formulating its general pregnancy warning for OTC drugs, FDA explained that it “chose[] the word ‘Warning’ as a signal word because it is more likely to attract the attention of consumers than the word ‘Caution.’”<sup>353</sup> Ten years later, in promulgating the final monograph for OTC antihistamine products, FDA reiterated this conclusion:

[T]he signal word “warning” is more likely to flag potential dangers so that consumers will read the information being conveyed. . . . Therefore, FDA has determined that the signal word “warning,” rather than the word “caution,” will be used routinely in OTC drug labeling that is intended to alert consumers to potential safety problems.<sup>354</sup>

The critical question in each case, however, is whether a particular risk deserves such attention.

Indiscriminately labeling every hazard, no matter how small, as a “Warning” is inappropriate, particularly when information about suspected chronic risks is unclear. Thus, “Warnings” for prescription drugs generally are based only on clinical data, though evidence of “serious animal toxicity” may suffice.<sup>355</sup> Evidence of carcinogenic potential from long-term animal studies normally should be included in the “Precautions” section of the package insert.<sup>356</sup> Statements about the acute health hazards of pesticides are introduced with signal words that vary according to the severity of the hazard, and EPA prohibits deviation from the signal words it has prescribed.<sup>357</sup> The tendency with respect to both acute and chronic risk labeling for other products, however, is to use the word “Warning” irrespective of the degree of risk or the strength of the scientific evidence underlying the statement. Regulators should adopt clearer guidelines for the consistent and discriminating use of hazard indicators, if not

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352. See Mark A. deTurck et al., *Uncertainty Reduction in Product Warnings: Effects of Fear in Signal Word and Hazard Statement*, 13 J. PROD. LIAB. 329, 336 (1991) (“[A] warning message is most effective when the signal word and hazard avoidance statement are consistent with respect to the level of fear they communicate.”). The authors also reported that consistency between color (red, orange, or yellow, in descending order of urgency) and the hazard statement were important. See Mark A. deTurck et al., *Uncertainty Reduction in Product Warnings: Effects of Fear and Color*, 13 J. PROD. LIAB. 339, 345 (1991).

353. 47 Fed. Reg. 54,750, 54,751 (1982).

354. 57 Fed. Reg. 58,356, 58,368 (1992). By comparison, in issuing its recent nutrition labeling regulations, FDA recognized that using the same descriptive terms for products containing different levels of a nutrient could confuse consumers. See 58 Fed. Reg. 2079, 2118 (1993) (“[A]djective formats lead consumers to miss quantitative differences between products when different nutrient levels are characterized by the same adjective.”).

355. 21 C.F.R. § 201.57(e) (1993).

356. *Id.* § 201.57(f)(5).

357. 40 C.F.R. § 156.10(h)(1)(i)(E) (1993).

across agencies, then at least within agencies or within categories of similar products.

### B. *Specifying the Hazard*

As the selection of signal words should reflect the degree of risk involved, the cautionary statement itself should accurately convey the nature of the hazard posed by the product. There is a danger that, in an effort to attract consumer attention to particular warnings, regulators may overstate a product's true risk. The objective should not "be to have the strongest impact possible but to have an impact that is most commensurate with the risk level that is posed by a product."<sup>358</sup> Consistent with such guidance, CPSC generally may not require the use of the same hazard statement for a product that "exhibits significantly dissimilar functional or risk characteristics when compared with the other products" for which that hazard statement is required.<sup>359</sup>

The Proposition 65 hazard statement ("WARNING: This product contains a chemical known to the State of California to cause cancer.") suggests a chronic health hazard far more serious than the one-in-100,000 lifetime cancer risk threshold that triggers the warning requirement. By way of comparison, the saccharin label statement mandated by Congress, is not designated as a "Warning," cautions only that the product "may be hazardous" and explains that the chemical "has been determined to cause cancer in laboratory animals."<sup>360</sup> Thus, the saccharin statement is substantially milder than the California warning even though the extrapolated lifetime human cancer risk from saccharin had been set at one-in-2500,<sup>361</sup> forty times greater than the Proposition 65 "no significant risk" threshold. The text of the California cancer warning statement more closely resembles the cigarette warning mandated by Congress in 1969,<sup>362</sup> even though the carcinogenic risks for these products may differ by several orders of magnitude. Consumers will be misled if such disparate risks are characterized in labeling as being equally serious.

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358. W. Kip Viscusi, *Predicting the Effects of Food Cancer Risk Warnings on Consumers*, 43 FOOD DRUG COSM. L.J. 283, 299 (1988) (criticizing the Proposition 65 requirements in part because California allows liquor stores to post a single sign to convey the warning while less risky food products must generally bear prominent individual warning statements on their labels).

359. *ASG Industries, Inc. v. CPSC*, 593 F.2d 1323, 1330 (D.C. Cir.), *cert. denied*, 444 U.S. 864 (1979). FDA announced that it would abide by this principle when it promulgated the TSS warning requirement for tampons. 47 Fed. Reg. 26,982, 26,984 (1982).

360. 21 U.S.C. § 343(o)(1) (1988).

361. *See supra* note 24.

362. *See Viscusi, supra* note 358, at 296-98 (describing consumer testing which demonstrated that "consumers view the Proposition 65 warning as stronger than the saccharin warning and at least as strong or stronger than the early cigarette warnings"); *see also* W. KIP VISCUSI, *REFORMING PRODUCTS LIABILITY* 136 (1991) ("[C]onsumers view the risk of getting cancer from eating breakfast cereal bearing a Proposition 65 warning as comparable to that of getting cancer from smoking 0.58 packs of cigarettes.").



Understated labeling statements also must specify the hazard posed by a product in clear terms. Warnings are vague if they report information such as the results from animal studies without describing the results in any terms that would allow consumers to assess the strength of the data. The saccharin statement, although it correctly avoids over-dramatizing the risk, provides a good illustration of the difficulties that accompany vague disclosures concerning chronic health risks extrapolated from studies in animals.

The main problem with such a warning is that it may be so equivocal or mysterious that it cannot even be taken into consideration by the consumer. The warning will not even produce an informed decision, let alone a particular decision that is socially desirable.<sup>363</sup>

The proposed warnings for products containing doxylamine and 4-MMPD share this same failing,<sup>364</sup> but at least these statements imply a human health risk of some type of cancer. References to completely unspecified health risks in the alcoholic beverages warning,<sup>365</sup> and the early cigarette warnings,<sup>366</sup> even fail to explain whether the hazard is chronic or acute. Such ambiguous warnings will undermine consumer confidence in the reliability of truly important label information.<sup>367</sup>

The need for clarity should not cause regulators to oversimplify hazards or obscure the degree of uncertainty underlying a risk estimate.<sup>368</sup> Generally, when physicians are the target audience, presenting meaningful risk estimates is not a problem. In revising its regulation on general prescription drug labeling, FDA observed that “[i]t is common for a warning to state that the product ‘may’ cause a hazard, where the relationship is not yet conclusively proven,

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363. Michael S. Yesley, *Afterword: Policy Issues in Risk Labeling*, in *PRODUCT LABELING*, *supra* note 171, at 315 (“Even if the risk and confidence in estimating the risk are low, . . . these factors do not justify presenting information that is virtually useless to the average consumer.”); *see also* NAS, *Food Safety Policy: Scientific and Societal Concerns* 7-13 - 7-14 (March 1979) (“[I]t is not easy to convey warnings about small and ambiguous risks. People have difficulty conceptualizing small-probability hazards, and abstract statistical information is much less compelling than concrete information.” (footnote omitted)).

364. *See supra* notes 67 & 135 and accompanying text. In the case of the 4-MMPD warning, FDA explained that there is “no reason to expect that consumers will interpret a warning that concerns the *nature* of the risk and that is phrased in general terms . . . as conveying information on the *size* of the risk in absolute terms or in comparison to other risks.” 44 Fed. Reg. 59,509, 59,516 (1979) (“Warning labels—including those for cigarettes and saccharin—simply do not purport to provide, and are not understood by the public as providing, that kind of information.”).

365. *See supra* note 54 and accompanying text.

366. *See supra* notes 36-37 and accompanying text.

367. *See Yesley, supra* note 363, at 316.

368. The NAS has emphasized that “[d]ata gaps and areas of significant disagreement among experts should be disclosed” when communicating risk information. NAS, *IMPROVING RISK COMMUNICATION* 170 (1989). “One pitfall is that of equating clarity with brevity. The message preparer’s goal should not be to gloss over the complexity and uncertainty of a risk but to reflect those qualities in plain language.” *Id.* at 167.

or to point out that the relationship between adverse animal findings and human consequences has not yet been determined."<sup>369</sup>

[I]ncluding the best available information on the degree of scientific certainty about a possible hazard, its frequency, severity, and other related information . . . [provides] clear and unambiguous information of use to the medical profession in making benefit-risk decisions on drug prescribing.<sup>370</sup>

Package inserts provide detailed scientific information about a drug's clinical pharmacology, adverse reaction profile, and the results of animal toxicology and *in vitro* mutagenicity assays, among other items.

As explained in Subpart D, consumers may find it very difficult to make sense of such information. In proposing to require PPIs, FDA recognized that many of the scientific concepts discussed in the package insert, no matter how simply written, "are difficult to convey to persons who lack professional training or experience in the use of prescription drug products."<sup>371</sup> Anticipated problems with comprehension by lay persons did not, however, deter FDA from proposing to require comprehensive though somewhat simplified PPIs based on the information contained in the package insert, and the PPIs would have included detailed information about carcinogenicity and mutagenicity.<sup>372</sup> By contrast, the proposed warnings for cosmetics containing 4-MMPD and OTC drug products containing doxylamine inappropriately gloss over precisely such information. If consumers are given the task of making their own risk-benefit calculations for potential carcinogens, they should also be provided with as much accurate information as possible.

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369. 39 Fed. Reg. 33,229, 33,232 (1974). FDA does not allow any "statement of differences of opinion with respect to warnings (including contraindications, precautions, adverse reactions, and other information relating to possible product hazards) required in labeling for food, drugs, devices, or cosmetics under the act." 21 C.F.R. § 1.21(c)(1) (1993). (Similarly, CPSC prohibits the use of disclaimers to accompany warnings on the labels of hazardous substances. 16 C.F.R. § 1500.122 (1993).) Unless FDA itself has prescribed cautionary statements that reflect the degree of uncertainty underlying a risk estimate, manufacturers are prohibited from conveying such information because it may undermine the warnings mandated by the agency. 39 Fed. Reg. at 33,232 ("[T]here is no basis to permit warnings to be discounted by an opinion that the warning is really not necessary at all. . . . [A] warning must be unencumbered and unambiguous."). FDA concluded that "where warnings are required, disclamatory opinions necessarily detract from the warning in such a manner as to be confusing and misleading." *Id.*; see also 40 Fed. Reg. 28,582, 28,583 (1975) ("[W]arnings about possible hazards associated with the use of a drug must, to be effective, remain undiluted by expressions of opinion discounting the risk.").

370. 40 Fed. Reg. 28,582, 28,584 (1975).

371. 44 Fed. Reg. 40,016, 40,026 (1979). In fact, some patients may consult professional labeling reprinted in the PDR and, although some of the terminology may be unfamiliar, they can glean basic risk information from it.

372. 44 Fed. Reg. 40,016, 40,026-27, 40,029 (1979). In addition, as more prescription drugs are switched to OTC status, labeling will become increasingly detailed. See Peter Barton Hutt, *A Legal Framework for Future Decisions on Transferring Drugs from Prescription to Nonprescription Status*, 37 FOOD DRUG COSM. L.J. 427, 438 (1982).

### C. *Explaining How to Avoid the Risk*

In addition to using signal words and text that are both clear and commensurate with the risk, regulators must advise consumers what steps they should take to avoid an identified hazard.<sup>373</sup> “The existence of [health] risks may mean little if it is not made clear what practical measures an exposed individual might use to avoid or reduce them.”<sup>374</sup> The labeling of drug products generally satisfies this criterion. In the case of package inserts for prescription drugs, which are meant to be read by physicians, FDA requires that the “Warnings” section describe serious adverse reactions, safety hazards, and the “steps that should be taken if they occur.”<sup>375</sup> Similarly, the precautionary labels for some consumer goods, especially OTC drugs, are framed primarily as directions for safe use.

Many other warning efforts, however, fail to describe how to avoid or minimize the hazard identified in the labeling statement. For example, it is unclear how the “Warning” required for cosmetic products whose safety has not been determined,<sup>376</sup> or chronic risk disclosures for OTC drugs,<sup>377</sup> will enhance purchase and use decisions. Such warnings are noncommittal because they convey information that scientists have had difficulty interpreting, and do so without even hinting what, if anything, consumers should do in response.<sup>378</sup> Vague warnings may provide comparative risk information in a gross sense, because consumers can select other products that do not include similar warning

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373. See William J. McGuire, *The Communication-Persuasion Model and Health-Risk Labeling*, in *PRODUCT LABELING*, *supra* note 171, at 106 (“[C]ompliance with risk-avoidance messages tends to increase with the amount of information given for how to avoid the risk rather than with amount of stress on the seriousness of the risk.”); David E. Kanouse & Barbara Hayes-Roth, *Cognitive Considerations in the Design of Product Warnings*, in *PRODUCT LABELING*, *supra* note 171, at 148-50 (emphasizing importance of both explaining nature of risk and providing “specific, action-oriented instructions”).

374. NAS, *supra* note 368, at 166. “Messages are more effective at producing behavior change when, in addition to producing understanding, they are specific about any desired response and proximate in time and place to that response.” *Id.* at 25; see also Viscusi, *supra* note 187, at 148-49 (1991) (“What matters is whether the warning conveys new information in a convincing manner. Warnings that are forms of persuasion or which are intended simply to serve as reminders will generally have less impact than those that provide new knowledge.”). Even when warnings restate the obvious, however, they may serve a valuable reminder function. 43 Fed. Reg. 25,544, 25,562 (1978) (“[M]any if not most warnings serve that purpose, and they remind people of important facts which, while obvious to many, might be overlooked by some.”).

375. 21 C.F.R. § 201.57(e) (1993). The section concerning “Overdosage” also requires giving concrete advice to the physician. *Id.* § 201.57(i).

376. *Id.* § 740.10(a).

377. See *supra* notes 134-142 and accompanying text. Similarly, “Proposition 65 is flawed because it informs the public only of the presence of risk at a level specified by a government agency, and does not provide the public with information to comprehend that risk.” Stenzel, *supra* note 227, at 516. *But see* Note, *Proposition 65’s Right-To-Know Provision*, *supra* note 227, at 704-05 (defending need to simplify message).

378. See SUSAN G. HADDEN, *READ THE LABEL: REDUCING RISK BY PROVIDING INFORMATION* 38 (1986) (“[I]t is unreasonable to expect individuals to process information that has confounded the experts.”). “Policy-makers like labeling precisely because it leaves these difficult choices to the individuals who will benefit from or suffer the risk. Unfortunately, many labels do not describe the hazards at all, and, of the ones that do describe the hazard, most give limited information about severity and none about probability.” *Id.* at 196.

statements. This argument assumes, however, that the substitutes have been subjected to similar testing for chronic risks, which often is not the case. Moreover, the argument assumes that consumers will be able to judge whether the chronic risk avoided by choosing a substitute outweighs possible increases in other risks or reductions in product effectiveness.<sup>379</sup> For instance, a consumer selecting an OTC cough-cold product may avoid products containing doxylamine because of a carcinogenicity warning in favor of other products with antihistamine ingredients, even though the substitutes may pose more serious but less frightening acute risks.

In the case of chronic risk disclosures, consumers may tend to infer that the disclosures suggest that the product should be avoided altogether,<sup>380</sup> even if the level of risk disclosed does not in fact justify avoidance of the product.<sup>381</sup> Where the risk is sufficiently great that avoidance may be merited, the warning statement should be more explicit about the nature of the risk and the circumstances under which the product should not be used, as is the case with the third-trimester pregnancy warning for products containing aspirin. If a risk is of such a magnitude that the product should be avoided in all cases, an outright prohibition makes more sense than a warning. If, however, a prohibition is considered unjustified in such a case, a warning requirement often would be equally inappropriate precisely "because the information necessary for an intelligent consumption decision cannot be provided."<sup>382</sup>

[FDA] does not believe that a warning or cautionary statement should be required for every possible question that might be raised about the

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379. See *infra* note 462 and accompanying text (discussing risk trade-offs between CFCs and certain hydrocarbon propellants); cf. *Public Citizen v. Young*, 831 F.2d 1108, 1113 (D.C. Cir. 1987) ("[M]akers of drugs and cosmetics who are barred from using a carcinogenic dye carrying a one-in-20-million lifetime risk may use instead a noncarcinogenic, but toxic, dye carrying, say, a one-in-10-million lifetime risk.").

380. FDA's labeling requirement for tampons includes a statement advising consumers that they can avoid the risk of getting TSS by not using tampons. 21 C.F.R. § 801.430(d)(4) (1993). In response to a comment calling this warning "unprecedented," the Agency noted that "[t]he significant difference between this statement and other warnings typically found on FDA-regulated products is that the statement itself sets forth the conclusion that is inherent in other such [FDA] warnings, viz., do not use the product if you wish to avoid the risk associated with it." 47 Fed. Reg. 26,982, 26,986 (1982); cf. *Dunn v. Lederle Laboratories*, 328 N.W.2d 576, 580 (Mich. App. 1982) ("Plaintiffs cite no authority for the proposition that a warning must include instructions on how to avoid a danger. . . . A danger is often avoided simply by refusing to use the dangerous product."); 16 C.F.R. § 1500.123 (1993) (whenever hazard statement itself implies precautionary measures, no separate statement of precautionary measures is needed under FHSA).

381. Contrast the direction on the labels of OTC dandruff products advising consumers to avoid prolonged use. See *supra* note 138. If FDA instead had selected a vague chronic risk statement to disclose the carcinogenicity of coal tar dyes, consumers may have avoided the products altogether even though the insignificant risk apparently did not justify such a response.

382. Cooper, *supra* note 171, at 301. For a defense of labeling as an appropriate regulatory strategy, see Cass R. Sunstein, *Informing America: Risk, Disclosure, and the First Amendment*, 20 FLA. ST. U. L. REV. 653 (1993).

safety of a product. A plethora of warnings about insubstantial questions would be difficult for consumers to evaluate.<sup>383</sup>

As explained in Part V(C) of this Article, public disclosure of such risks may be better accomplished in other ways.

Nonetheless, lawmakers frequently pass the burden of making decisions about ambiguous product risks to consumers. When FDA decided to prohibit most uses of saccharin, Congress interceded with a labeling requirement describing in only general terms the results of the animal bioassays. FDA's warning for cosmetics containing 4-MMPD placed primary decisionmaking responsibility in the hands of consumers but failed to equip them with the information necessary to make sense of the warning. In the case of the general pregnancy warning for OTC drugs, FDA specifically denied that the warning was intended "to shift responsibility for determining the product's safety to consumers."<sup>384</sup> The pregnancy warning was directed to an easily identified subpopulation already under medical supervision in most cases, and it was based on well-documented concerns with drugs intended for systemic absorption.<sup>385</sup> By contrast, generalized disclaimers that the safety of a product is unproven and carcinogen warnings like those required under Proposition 65 are directed to all purchasers of a product. Although they have the advantage of preserving consumers' freedom of choice, such warnings give no hint of what consumers should do in response to the information provided. As explained in Part V(B), exaggerated or uninformative warning statements serve only to distort consumer choices.

#### D. *Ensuring Consumer Comprehension*

In addition to characterizing hazards accurately and explaining how to avoid risks, warning statements must be clear and should contain enough detail to ensure comprehension of the risk information that is presented. Although, as explained in the previous sections, warning labels should provide accurate and detailed risk information, there is a countervailing need to guard against overwhelming consumers with too much information. Because risk messages "cannot include all the details known to science and still be read and understood by nonexperts," persons who design such messages must "omit some information and highlight other information."<sup>386</sup> In connection with its recent nutrition labeling regulations, FDA noted that studies "have generally shown

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383. 43 Fed. Reg. 1101, 1104 (1978).

384. 47 Fed. Reg. 54,750, 54,751 (1982).

385. *Id.* at 54,754 ("FDA concludes that the warning statements required are those that are scientifically documented, clinically significant, and important for the safe and effective use of the products by average consumers.").

386. NAS, *supra* note 368, at 82.

that consumers prefer the largest amount of information offered but perform best with limited amounts of information specifically related to the task."<sup>387</sup>

Consumer research conducted by industry and by FDA demonstrated that simpler, less cluttered label formats help consumers to make comparisons between products. . . . The agency agrees that simplicity and lack of clutter are important criteria in selecting a format. However, enough effective information must be presented to make the nutrition label useful.<sup>388</sup>

In designing warning statements, therefore, a balance must be struck between simplicity and specificity.

The FD&C Act requires that label information be presented in such "terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."<sup>389</sup> The regulation governing OTC drug products is even more explicit.

Labeling . . . shall state . . . warnings against unsafe use, side effects, and adverse reactions in such terms as to render them likely to be read and understood by the ordinary individual, *including individuals of low comprehension*, under ordinary conditions of purchase or use.<sup>390</sup>

Agency labeling requirements sometimes fail to adhere to these guidelines. For example, suggestions that OTC products include warnings about possible carcinogenicity in animals will make little sense to persons of low or even ordinary comprehension. Similarly, several of FDA's cosmetic labeling requirements do not provide precautionary information in a manner that is likely to be read and understood by the consumer, much less acted upon in an appropriate fashion.<sup>391</sup>

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387. 58 Fed. Reg. 2079, 2119 (1993) (citations omitted).

388. *Id.* at 2122 & 2132; *see also* 59 Fed. Reg. 3752 (1994) (CDC proposal to simplify vaccine information materials); Kanouse & Hayes-Roth, *supra* note 373, at 153 ("[C]onsumers may be more inclined to act on a warning that they perceive as complete and accurate than on an equally comprehensible warning that offers little justification for its conclusions.").

389. 21 U.S.C. § 352(c) (1988).

390. 21 C.F.R. § 330.10(a)(4)(v) (1993) (emphasis added). "Studies indicate that a warning message is more likely to be remembered over the long-term if it presents specific rather than general information. Also, research indicates that labels must be written clearly and in a manner that can be understood by target audiences." Assistant Secretary of Health, HHS, *Review of the Research Literature on the Effects of Health Warning Labels: A Report to the United States Congress* 4 (June 1987); *see also* 43 Fed. Reg. 25,544, 25,553 (1978) (revising proposed warnings for OTC nighttime sleep-aids "in the interests of conciseness, legibility, and clarity").

391. *See supra* notes 60, 67, 134-142 and accompanying text.

Target audiences will have differing levels of sophistication. Because of the role of physicians with respect to prescription drugs and devices, precautionary information accompanying these products may be quite detailed and complex. Most other warning labels are directed to lay consumers. When hazard information is provided directly to these users, the risk message must be simplified somewhat and expressed in concrete terms if it is to be comprehended by the majority of readers.<sup>392</sup> Even if a reasonably sophisticated individual could grasp the message behind, for instance, a carcinogen warning, consumers of average or below average comprehension surely could not appreciate its meaning or purpose.

It is estimated that nearly ten percent of the United States' population is functionally illiterate.<sup>393</sup> A smaller but still significant percentage of the population is only able to speak a language other than English.<sup>394</sup> Such statistics have prompted some courts to demand that manufacturers use dual language labeling or pictograms to alert consumers who may have difficulty reading English.<sup>395</sup> FDA permits multilingual labeling of most products, and in some cases it has permitted or required the use of symbols.<sup>396</sup> EPA is somewhat less flexible with regard to multilingual labeling,<sup>397</sup> but both it and CPSC require the use of the skull-and-crossbones symbol on poisonous products.<sup>398</sup> Canada has developed an elaborate pictogram system to convey certain types of risk information such as degrees of flammability.<sup>399</sup> Serious difficulties would be encountered, however, if one attempted to supplement or replace more complicated textual warnings with pictographs or other symbols.<sup>400</sup>

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392. Some commentators have suggested the use of a common risk metric to facilitate consumer decisions about potentially hazardous products. See, e.g., McGuire, *supra* note 373, at 106. Efforts to compare dissimilar risks with some baseline (e.g., flying from Boston to New York) should be avoided, however, "as they have often either confused message recipients or irritated them because they were seen as unfair or manipulative." NAS, *supra* note 368, at 173; see also *id.* at 97 ("The easiest way to avoid comparing apples and oranges is to compare the risk associated with the same hazard at different times or risks associated with different options for achieving the same purpose.").

393. See William Celis III, *Study Says Half of Adults in U.S. Can't Read or Handle Arithmetic*, N.Y. TIMES, Sept. 9, 1993, at A1, A22 (adding that an even greater percentage are barely functional); Lee A. Daniels, *Illiteracy Seen as Threat to U.S. Economic Edge*, N.Y. TIMES, Sept. 7, 1988, at B8.

394. See Department of Commerce, STATISTICAL ABSTRACT OF THE UNITED STATES xii (112th ed. 1992) (preliminary data from 1990 census reveal that over five percent of the population over five years of age speaks a foreign language and cannot speak (or, presumably, read) English very well).

395. See *supra* notes 271-272.

396. See *supra* note 122. Persons advocating bilingual labeling sometimes point to dual language labeling in Canada. See Consumer Packaging and Labelling Regulations, C.R.C., c.417, §§ 6(2), 6(8) (1990). FDA has specifically rejected the analogy because Canadian regulations do not mandate the inclusion of as much information as does FDA. See 50 Fed. Reg. 1833, 1836-37 (1985) (discussing requirement of pictograms and symbols but not multilingual labels in labeling of infant formulas).

397. See *supra* note 196.

398. See *supra* note 191. Because hazards to young children generally cannot be addressed adequately through cautionary labeling, Congress has opted for design standards in such cases. See *supra* note 14.

399. See *supra* note 188.

400. See Ramirez v. Plough, Inc., 25 Cal. Rptr. 2d 97, 101 n.3 (1993) ("[A]lthough symbols and pictograms can be used effectively to warn that a substance is flammable or toxic, . . . it is doubtful that they are at present able to convey the more complex warning information typically required for

In addition to limiting the possible effectiveness of warning label requirements,<sup>401</sup> high levels of functional illiteracy may have important distributional consequences. Some commentators have suggested that information provision is a regressive policy because it provides costly information of interest only to educated consumers,<sup>402</sup> who, if they respond to this information by avoiding riskier products in favor of substitutes, may affect prices in such a way that poorer individuals will consume or otherwise be exposed to a disproportionate share of the riskier products.<sup>403</sup> Of course, warning requirements may lead to product reformulations that benefit everyone,<sup>404</sup> and more direct forms of safety regulation such as design standards may have similar distributional effects by increasing prices.<sup>405</sup> In any case, the fear of distributional consequences should not deter regulators from demanding warnings (or design standards) when appropriate, but such concerns should underscore the need to ensure that risk information be comprehensible and meaningful to as many consumers as possible.

### E. Evaluating Effectiveness

Several commentators have stressed the need to undertake consumer studies in advance of mandating a warning statement on a particular product.<sup>406</sup> Only rarely, however, have agencies undertaken such studies.<sup>407</sup> Although courts have

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nonprescription drugs."); *Broussard v. Continental Oil Co.*, 433 So. 2d 354, 357-58 (La. App.) (rejecting symbols proposed by plaintiff's expert because they were "unclear and subject to different interpretations"), *cert. denied*, 440 So. 2d 726 (La. 1983); HADDEN, *supra* note 378, at 235 (noting that "it is difficult to develop pictograms that are easily associated with hazards," and that "the number of hazards is so great that it is impossible to devise pictograms to indicate them all"); Mark R. Lehto & James M. Miller, *The Effectiveness of Warning Labels*, 11 J. PROD. LIAB. 225, 238-45 (1988).

401. See Cooper, *supra* note 105, at 617.

402. See HADDEN, *supra* note 378, at 226; Michael B. Mazis, *An Overview of Product Labeling, and Health Risks*, in *PRODUCT LABELING*, *supra* note 171, at 8. Sales of diet soft drinks did not increase as rapidly in educated as in undereducated neighborhoods after the saccharin warning label appeared, see Raymond C. Stokes, *Consumer Research on Food-Label Information*, in *PRODUCT LABELING*, *supra* note 171, at 84, but this may reflect an overreaction by well-educated persons rather than an underreaction by those who are less well educated.

403. See HADDEN, *supra* note 378, at 144; Note, *Health Regulation of Naturally Hazardous Foods*, *supra* note 106, at 1045 n.139.

404. See Howard Beales, *Benefits and Costs of Label Information Programs*, in *PRODUCT LABELING*, *supra* note 171, at 248 ("All consumers who use these products benefit from the information even though only a small number actually read the labels . . . [because of] product changes as a result of the competitive process.").

405. See HADDEN, *supra* note 378, at 226.

406. See, e.g., VISCUSI, *supra* note 362, at 144-45; Yesley, *supra* note 363, at 313 (criticizing the lack of any "empirical justification" for many warning requirements).

407. See, e.g., 47 Fed. Reg. 54,750, 54,754 (1982) (rejecting suggestion that consumer studies be undertaken before imposing third-trimester pregnancy warning for OTC aspirin products). Courts have demanded that CPSC requirements for warning labels be proven effective but have stopped short of requiring consumer behavior studies. See *Consumer Fed'n of America v. CPSC*, 883 F.2d 1073, 1078 (D.C. Cir. 1989) (rejecting argument that such studies were a statutory prerequisite for methylene chloride warning requirement); *Aqua Slide 'N' Dive Corp. v. CPSC*, 569 F.2d 831, 841-42 (5th Cir. 1978) ("The evidence that the signs would reduce the risk rests more on inference than it does on proof."). When it recently



identified some general factors in defining the duty to provide adequate warnings, judges generally have not demanded that consumer studies be introduced to evaluate this question. Instead, jurors are left to make judgments about the adequacy of challenged warnings,<sup>408</sup> sometimes but not invariably with the assistance of testimony from risk communication experts for one or both parties at trial.<sup>409</sup>

Significant difficulties would attend efforts to study the effectiveness of warning programs, whether these studies are undertaken prospectively or retrospectively. The Administrative Conference of the United States has noted that the “[f]ailure to clarify whether the primary purpose [of agency risk communication programs] is simply to inform and educate persons at risk, or to produce actual behavioral changes, has hindered evaluation and reform efforts.”<sup>410</sup> The NAS added that:

Although risk messages are sometimes judged against a criterion of behavior change, this is not an appropriate test of whether an individual has made an informed choice. It is possible for an individual, fully informed of the risks, to choose to engage in hazardous behaviors . . . .<sup>411</sup>

In the case of warnings concerning the risk of acute illness or injury, changes in the rate of that illness or injury may be correlated with the warning effort. For example, the incidence of toxic shock syndrome (TSS) has declined sharply in the last decade,<sup>412</sup> the decline in TSS appears to have more to do with changes in tampon design than with the warning efforts.<sup>413</sup> Moreover, the informational effects of FDA-mandated labeling cannot be readily disentangled from the effects of extensive media coverage of the problem. Cases of Reye syndrome also have decreased since FDA required a warning for OTC products

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revised the format of the nutrition label on food products, however, FDA relied heavily on consumer research. See 58 Fed. Reg. 2079, 2115 (1993) (“Behavior-based performance measures . . . are generally accepted as the more reliable and valid way to evaluate the consequences of information displays on consumer perception and understanding.”).

408. See *Ferebee v. Chevron Chem. Co.*, 552 F. Supp. 1293, 1304 (D.D.C.) (“The Court can think of no question more appropriately left to a common sense lay judgment than that of whether a written warning gets its message across to an average person.”), *aff’d*, 736 F.2d 1529 (D.C. Cir. 1982), *cert. denied*, 469 U.S. 1062 (1984); *Streich v. Hilton-Davis, Div. of Sterling Drug*, 692 P.2d 440, 443 (Mont. 1984) (“Any layman could understand the insufficiency of the warning. Expert testimony was not necessary.”); *cf. Wyeth Lab., Inc. v. Fortenberry*, 530 So. 2d 688, 692 (Miss. 1988) (“The adequacy of a warning addressed to the medical community may fall into the category of issues requiring expert testimony.”).

409. See, e.g., *Baroldy v. Ortho Pharmaceutical Corp.*, 760 P.2d 574, 588-89 (Ariz. Ct. App. 1988); John G. Kreifeldt, *A Deductive Method for Treating Expert Opinions: An Application to Warnings and Instructions*, 14 J. PROD. LIAB. 225 (1992).

410. 55 Fed. Reg. 13,538, 13,539 (1990) (draft recommendation on “Risk Communication as a Regulatory Alternative for Protecting Health, Safety and the Environment”).

411. NAS, *supra* note 368, at 80.

412. See 39 MORB. & MORT. WEEKLY REP. 421 (1990).

413. *Id.* at 422.

containing aspirin, but here again it is difficult to attribute the decline to labeling alone rather than the Agency's simultaneous public education campaigns.<sup>414</sup>

It is even more difficult to judge the effectiveness of warning labels concerning chronic risks. Studies often look to changes in consumption patterns in such cases. For instance, "studies of the impact of the saccharin warning label concluded that the warning label did have a moderate, but statistically significant, impact upon sales of diet soft drinks in grocery stores."<sup>415</sup> These consumption changes may, however, reflect an overreaction by consumers to the level of risk suggested by the disclosure statement. In the case of cigarettes, extensive publicity about the hazards of smoking has had a noticeable effect on consumption, but again it is impossible to segregate the independent impact of warning labels.<sup>416</sup> The apparent impact of mandatory warnings concerning alcoholic beverages on patterns of usage has been disappointing to date.<sup>417</sup>

#### F. Summary

There are a number of important considerations that should be taken into account when designing or reviewing cautionary labeling statements to ensure that risk information is conveyed in an appropriate fashion. Risk statements must use proper signal words, specify the nature of the hazard, explain how to avoid the hazard, and be comprehensible to consumers. Existing labeling efforts often are deficient in at least one respect (in some cases unavoidably so), and sometimes deficient in several. Lack of appropriate selectivity is one recurring error that is discussed at greater length in the next Part.

#### V. The Hazards of Overwarning

Even if it were possible to include cautionary information about every potential hazard in product labeling, it would be undesirable to do so for a number of reasons. The proliferation of warnings may dilute the impact of truly important cautionary information. By the same token, it may cause consumers

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414. 53 Fed. Reg. 21,633, 21,634 (1988); 40 MORB. & MORT. WEEKLY REP. 88, 89 (1991).

415. Assistant Secretary of Health, HHS, *supra* note 390, at 4-5 ("One study concluded that the warning label resulted in a 6 percent reduction in diet soft drink sales below expected sales levels.").

416. See R. Dennis Murphy, *Consumer Response to Cigarette Health Warnings*, in *PRODUCT LABELING*, *supra* note 171, at 13, 17 (describing FTC study); cf. Bethany K. Dumas, *Adequacy of Cigarette Package Warnings*, 59 TENN. L. REV. 261, 297-301 (1992) (identifying numerous alleged shortcomings of cigarette warnings).

417. See Michael E. Hilton, *An Overview of Recent Findings on Alcoholic Beverage Warning Labels*, 12 J. PUB. POL. & MKTG. 1, 3-4 (1993). Studies of information disclosure in other contexts confirm the problems that may be encountered when providing complicated information to consumers. See, e.g., Jeffrey Davis, *Protecting Consumers from Overdisclosure and Gobbledygook: An Empirical Look at the Simplification of Consumer-Credit Contracts*, 63 VA. L. REV. 841 (1977).

to overreact to information about relatively inconsequential risks. Notwithstanding these concerns, courts and regulators have demanded that an ever-growing number of warning statements appear on product labels.

#### A. *Causes of Excessive Warnings*

Decisionmakers often fail to take into account the need for selectivity in the design of warning statements. Courts in particular seem oblivious to the overall effect of their many decisions regarding the need to warn of individual and often trivial risks. "[T]he legal system's apparent preference for comprehensive warnings is less the result of a considered evaluation of the warnings problem than the net effect of hundreds of narrowly focused products liability cases."<sup>418</sup> Typically, courts view the marginal costs of providing additional warnings as insignificant.<sup>419</sup> Such a narrow focus on the low apparent cost of relabeling can lead to serious mischief when deciding what warnings should have been given. The premise that hazard statements on product labels are essentially costless erroneously suggests that all potential risks, no matter how remote, should be disclosed.

The low perceived cost of labeling revisions relates both to adding new warnings and to enhancing the prominence of existing warnings.<sup>420</sup> Thus, even when a manufacturer has the foresight to mention the particular injury suffered by a plaintiff, it may be held liable for not making the reference to that risk sufficiently eye-catching, no matter how trivial the risk is in comparison to the other hazards discussed in the labeling. At present, courts impose no penalties for overwarning, only, for failing to provide what they deem to be adequate warnings. As a consequence, manufacturers have an incentive to provide extremely detailed and comprehensive warnings rather than meaningful cautionary statements about only truly important risks.<sup>421</sup> There is also an incen-

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418. Victor E. Schwartz & Russell W. Driver, *Warnings in the Workplace: The Need for a Synthesis of Law and Communication Theory*, 52 U. CIN. L. REV. 38, 60-61 n.108 (1983) ("When a person is injured by a very remote risk, the remoteness of the risk tends to be obscured by the reality of plaintiff's injury. Courts generally do not ask how many other risks the manufacturer might also be required to warn about.").

419. As one court explained, the cost of giving an adequate warning, "amounting only to the expense of adding some more printing to a label, . . . would be of minimal consequence. . . ." *Moran v. Fabergé, Inc.*, 332 A.2d 11, 15 (Md. 1975); see also *Ross Lab. v. Thies*, 725 P.2d 1076, 1079 (Alaska 1986); *Cooley v. Carter-Wallace Inc.*, 478 N.Y.S.2d 375, 376-77 (N.Y. App. Div. 1984) ("Since the cost of providing warnings is often minimal, the balance usually weighs in favor of an obligation to warn."); *Dambacher v. Mallis*, 485 A.2d 408, 423 (Pa. Super. Ct. 1984), *appeal dismissed*, 500 A.2d 428 (Pa. 1985).

420. See Viscusi, *supra* note 187, at 151 ("There are always additional manipulations of the warnings that are possible to make the risk information seemingly more prominent.").

421. See Schwartz & Driver, *supra* note 418, at 60; Scarlett, *supra* note 163, at 34. As an extreme example, the instructions for one company's Batman costume apparently include the following cautionary statement: "Cape does not enable user to fly." Dave Barry, *You Can Say That Again*, WASH. POST MAG., Sept. 19, 1993, at 52.

tive to highlight all cautionary information as significant.<sup>422</sup> These legal incentives are tempered, of course, by countervailing marketing pressures and practical constraints such as the size of product labels.

A few courts have acknowledged the need for selectivity when conveying risk information in product labeling. For instance, the United States Court of Appeals for the D.C. Circuit once observed that "[f]ailure-to-warn cases have the curious property that, when the episode is examined in hindsight, it appears as though addition of warnings keyed to the particular accident would be virtually cost free."<sup>423</sup> As the court, however, elaborated:

Plaintiff's analysis completely disregards the problem of information costs. . . . He discounts altogether the warnings in the pamphlet, without even considering what the canister warning would have looked like if [the manufacturer] had supplemented it not only with the special items he is personally interested in—in hindsight—but also with all other equally valuable items (*i.e.*, "equally" in terms of the scope and probability of the danger likely to be averted and the incremental impact of the information on user conduct).<sup>424</sup>

A product may pose two or three significant hazards along with a dozen identifiable but relatively trivial risks. An effective warning label might be able to address the significant hazards, but a duty to warn of every foreseeable risk would result in a substantially longer label or less detailed discussion of the important risks to avoid.

A pair of 1983 decisions involving failure-to-warn claims against a power tool manufacturer recognized the difficulties that would arise if the more prominent warnings urged by the plaintiffs were required for all equally serious

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422. See Cooper, *supra* note 334, at 237 ("The incentive is to issue warnings that the manufacturer thinks have the best chance of satisfying a jury . . ."); Henderson & Twerski, *supra* note 240, at 318-19; see also Viscusi, *supra* note 187, at 158 ("[I]f one were to adopt a warnings strategy with the objective of minimizing one's risk of liability, the solution would be to box and put in large bold lettering all warnings pertaining to products . . .").

423. Cotton v. Buckeye Gas Prod. Co., 840 F.2d 935, 937-38 (D.C. Cir. 1988).

424. *Id.* at 938; see also Ramirez v. Plough, Inc., 25 Cal. Rptr. 2d 97, 105-06 (Cal. 1993) (Multilingual labeling of OTC drug products "might prove ineffective or even counterproductive if the warning inserts became so large and cumbersome that a user could not easily find the warning in his or her own language."); Ingram v. Hook's Drugs, Inc., 476 N.E.2d 881, 887 n.4 (Ind. Ct. App. 1985) (rejecting suggestion that patient should have been given precautionary information contained in package insert for Valium, which included over 20 cautionary instructions and 32 listed side effects, because "[s]uch a voluminous warning would only confuse the normal consumer and be of dubious value"); Vallillo v. Muskin Corp., 514 A.2d 528, 531 n.3 (N.J. Super. Ct. App. Div. 1986) ("Warning labels cannot be effective if they take on the characteristics of drug package inserts."), *cert. denied*, 546 A.2d 540 (N.J. 1988); W. PAGE KEETON, PROSSER & KEETON, THE LAW OF TORTS § 96 (5th ed. 1984), at 686 ("Those who argue for warning as the solution to latent design defects labor under a naive belief that one can warn against all significant risks.").

risks posed by the products.<sup>425</sup> In both cases, the tool itself carried an instruction directing the user to read the accompanying owner's manual for safety information, and the risk encountered by each plaintiff was clearly warned against in the manual. Both plaintiffs claimed, however, that the tools themselves should have carried a label warning against the particular hazard that caused their injuries, a proposition rejected by both courts.

In this case, the injury was caused by explosion, but it could just as easily have been caused by failure to observe any of the other nineteen safety precautions. To require that one explicit warning be placed on the saw would be to require all twenty.<sup>426</sup>

The courts thus avoided the common pitfall of evaluating the plaintiff's failure-to-warn claim in isolation and without regard to all of the equally pertinent risks that also might have to be warned against on the label. The inquiry in these two cases was simplified somewhat because the owner's manuals contained a large but finite set of hazard statements. Courts encounter greater difficulty when no warning against plaintiff's injury is given anywhere or when it is unclear how many other risks of a comparable magnitude exist and might necessitate a similar warning statement.<sup>427</sup>

Although judicial recognition of the problem of information costs may be increasing, the majority of failure-to-warn cases continue to focus narrowly on the failure to warn adequately of the particular injury suffered by the plaintiff,

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425. See *Scott v. Black & Decker, Inc.*, 717 F.2d 251 (5th Cir. 1983); *Broussard v. Continental Oil Co.*, 433 So. 2d 354 (La. Ct. App.), *cert. denied*, 440 So. 2d 726 (La. 1983); see also *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 815-16 (5th Cir.) (rejecting plaintiff's claim that the contraindications for Accutane should have been broader than those required by FDA), *cert. denied*, 112 S. Ct. 2304 (1992); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003-04 (4th Cir. 1992) (rejecting plaintiff's proposed contraindication for an IUD, noting that any additional suggested warning "must bear some reasonable relation to the 1.84% risk" of pelvic inflammatory disease and resulting ectopic pregnancy).

426. *Scott*, 717 F.2d at 254. In the other case, the owner's manual included eighteen warnings, and the plaintiff conceded that as many as ten of these should have appeared directly on the label, while the manufacturer took the position that there was no basis for excluding the other eight. The court held that none need appear on the label:

As a practical matter, the effect of putting at least ten warnings on the drill would decrease the effectiveness of all the warnings. A consumer would have a tendency to read none of the warnings if the surface of the drill became cluttered with the warnings. Unless we should elevate the one hazard of sparking to premier importance above all others, we fear that an effort to tell all about each hazard is not practical either from the point of view of availability of space or of effectiveness. We decline to say that one risk is more worthy than another.

*Broussard*, 433 So. 2d at 358.

427. In one case, for instance, where the trial court had granted the manufacturer a judgment notwithstanding the verdict partly because the plaintiff's failure-to-warn claim ignored the trade-offs that a more specific warning would have required, the appellate court reversed, explaining that "the jury is perfectly capable of assessing whether the proposed warning would be unreasonable because of possible cost or confusion." *Marchant v. Dayton Tire & Rubber Co.*, 836 F.2d 695, 701 (1st Cir. 1988).

no matter how trivial the risk of that injury is as compared to other risks posed by the product. This is not to say that in all instances a court should decline to find a warning inadequate because of such information costs. In some cases, a narrow holding that a certain type of serious risk was not made sufficiently clear in the existing labeling may be defensible.<sup>428</sup> For the most part, however, the common law duty to warn has been applied by the courts without sufficient care.

Lawmakers sometimes suffer from the same myopia, resorting to product labeling as a default option for controlling risks because of its perceived ease and flexibility.<sup>429</sup> "The low direct cost of label information has seemingly beguiled many would-be regulators into requesting even more information on labels."<sup>430</sup> Agencies sometimes impose labeling requirements without giving any real consideration to the impact on the label as a whole, tacking on additional warning statements as new hazards are identified. FDA's cosmetic labeling regulations provide a good illustration of this problem.<sup>431</sup> By contrast, when

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428. See, e.g., *Ayers v. Johnson & Johnson*, 818 P.2d 1337, 1342 (Wash. 1991) (rejecting argument that imposition of liability for failure to warn of risks of aspiration of baby oil by infant would force manufacturers to "deluge" consumers with "indiscriminate warnings" of remote risks associated with aspiration of other common products). The Court added,

Our holding is limited to the proposition that baby oil, because it is intended for use on and around babies, may be the proximate cause of injuries due to aspiration if sold without an adequate warning of the danger of such injuries. We reject the notion that any product with physical properties similar to, or as dangerous as, those of baby oil may for that reason alone create manufacturer liability for failure to warn. Because our holding is limited in this way, we reject the argument that upholding the jury's verdict . . . will dramatically encourage overwarning.

*Id.* at 1343. Of course a cautious manufacturer, fearing what a somewhat less reasonable court might decide in a future case, may feel compelled to add warnings about aspiration by babies of common food products such as milk or apple sauce. (CPSC already requires warnings for products containing mineral oils because of the risk of aspiration. 16 C.F.R. § 1500.14(b)(3)(ii) (1993).)

429. See HADDEN, *supra* note 378, at 258-59 ("Most new risk control laws incorporated a labeling requirement because labeling seems to be a relatively benign form of regulation: low in cost and preserving flexibility of individual action."). One of the sponsors of the alcohol labeling legislation asserted that "warning labels are the quickest, cheapest, and probably the most effective means for imparting the necessary knowledge." *Hearings Before the Subcomm. on the Consumer of the Senate Comm. on Commerce, Science, and Transportation*, 100th Cong., 2d Sess. 13 (1988) (statement of Rep. John Conyers, Jr.); see also Jeff MacNelly, *Shoe* (Tribune Media Services, Inc., Oct. 28, 1988) (proposing as "the all-purpose warning label" the following: "The Surgeon General has determined we are all doomed.").

430. Beales, *supra* note 404, at 249. Ironically, consumer groups seem equally short-sighted in their assessment of the potential costs associated with warning labels. See, e.g., William B. Schultz, *Labels, Bans, and Consumer Preferences*, in *PRODUCT LABELING*, *supra* note 171, at 221 ("Labeling is a simple and inexpensive means of conveying information to consumers about the products they buy."). The author, then a director of the Public Citizen Litigation Group, asserted that "consumers should be given *all* the information which is available about the risks associated with the product," because, "even if we cannot prove in advance that labeling will affect consumer conduct, there is considerable value in giving information to consumers so that they bear some responsibility for their choice." *Id.* at 224 (emphasis added); see also *FOOD CHEM. NEWS*, Feb. 15, 1993, at 76 (describing lawsuit brought by a public interest organization challenging USDA's failure to require warning labels describing risks of bacterial contamination in meat and poultry products).

431. See *supra* notes 60-67 and accompanying text.

they engage in rulemaking efforts that simultaneously affect many aspects of a product label, agencies are somewhat more attentive to the marginal costs of including additional information.<sup>432</sup>

State lawmakers sometimes view labeling requirements as an indirect way to regulate products that are otherwise subject primarily to federal control. Warning requirements may be thought of as placing less of an undue burden on interstate commerce than would more direct design requirements or outright prohibitions. The warning provisions of Proposition 65, for example, seek to encourage product reformulation,<sup>433</sup> leading one defender of the law to assert:

Th[e] feared proliferation of warnings will not necessarily occur, because those who produce toxic substances or use them in the workplace may substitute other substances for the listed chemicals that trigger Proposition 65's warning requirement. If unlisted chemicals displace listed ones, there will be no overwarning problem because those substitute chemicals will require no warnings.<sup>434</sup>

Reformulation may not, however, prove to be feasible for many products.

Thus, courts and lawmakers share the blame for encouraging or demanding excessive consumer product warnings. In particular, fears of tort liability have created distorted incentives to add warnings to product labeling. The ultimate irony of reliance on warnings to convey information about insignificant risks is that overwarning eventually may incur penalties from the very same courts that have created the pressures to overwarn in the first place. It seems to be only a matter of time before a plaintiff succeeds in bringing an inadequate warning claim premised on the argument that, although a completely accurate statement of the risk had been provided, the pertinent warning lacked sufficient prominence because it was lost among the clutter of too many other cautionary

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432. For instance, FDA took into account the trade-offs to be made when it substantially revised nutrition labeling requirements for food products. See 58 Fed. Reg. 2079, 2107 (1993) ("Not only would space constraints not allow for [the inclusion of all information related to healthy dietary practices], but the large amount of information would interfere with consumers' abilities to use the information of the greatest public health significance."). Similarly, FDA reduced the number of warnings proposed for use on OTC topical first aid antiseptic products from seven to four after "recogniz[ing] that it is not necessary or even possible to identify every improper use of a drug that could occur and to list such information on the label." 56 Fed. Reg. 33,644, 33,654 (1991); see also 44 Fed. Reg. 37,434, 37,448 (1979) ("agree[ing] that information should not be unnecessarily duplicated in [prescription] drug labeling").

433. See *supra* note 229.

434. Note, *Proposition 65's Right-To-Know Provision*, *supra* note 227, at 704 (footnote omitted).

statements on the label.<sup>435</sup> Although such an outcome is not to be encouraged, it would bring the failure-to-warn case law full circle.

Excessive warnings also may face threats of regulatory enforcement actions. As mentioned earlier, EPA prohibits the use of overly alarming signal words in the labeling of pesticide products<sup>436</sup> and FDA strictly controls the cautionary labeling allowed for OTC medications.<sup>437</sup> FDA prescription drug regulations are a significant restraint to those who would attempt to insulate themselves from products liability exposure by mentioning or highlighting unsubstantiated or insignificant risks.<sup>438</sup> The Agency generally frowns upon and will not approve defensive labeling. For instance, FDA has rejected manufacturers' proposals to contraindicate or otherwise warn against use of their drugs during pregnancy, proposals evidently prompted by the valid fear that birth defects (which are certain to occur in some percentage of women) might wrongly be associated with the use of those drugs during pregnancy and therefore expose the manufacturer to potentially meritless but costly products liability claims.<sup>439</sup> A manufacturer could not, in pursuit of satisfying its common law duty to warn, ignore FDA's decision without risking administrative enforcement actions. In most cases, however, agencies do not restrict so clearly the ability to include additional or more prominent hazard statements in product

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435. Cf. *Karns v. Emerson Elec. Co.*, 817 F.2d 1452, 1457 (10th Cir. 1987) (holding that jury could reasonably find warnings accompanying mechanized yard tool inadequate, in part because sheer number of different safety rules and precautions appearing in owner's manual (24 in all) may have undermined clarity of instructions against using tool when other persons were in vicinity); *Hahn v. Sterling Drug, Inc.*, 805 F.2d 1480, 1482 (11th Cir. 1986) (FDA-mandated warning to keep product out of children's reach may have been inadequate for OTC analgesic in light of fact that "the same warning appears on numerous products that are not harmful"); *Spruill v. Boyle-Midway, Inc.*, 308 F.2d 79, 86 (4th Cir. 1962) (warning of danger associated with ingestion of furniture polish should not have been given lesser prominence on label than danger of combustion); *Leday v. Clairol, Inc.*, 571 So. 2d 866, 870 (La. Ct. App. 1990) (finding that cautionary information on label of hair dye product satisfied duty to warn in part because it "was not obscured by numerous other warnings and instructions"); *Walker v. Maybelline Co.*, 477 So. 2d 1136, 1139 (La. Ct. App. 1985) ("The warning was buried in a list of instructions. . ."), *cert. denied*, 481 So. 2d 1333 (La. 1986). Apparently no court has yet held a defendant liable for overwarning. See STEVEN GARBER, *PRODUCT LIABILITY AND THE ECONOMICS OF PHARMACEUTICALS AND MEDICAL DEVICES* 134 (1993).

436. 40 C.F.R. § 156.10(h)(1)(i)(E) (1993).

437. See 21 C.F.R. § 330.1(c)(2)(vi) (1993) (warnings for OTC drugs may not deviate from language required by applicable monographs); 56 Fed. Reg. 63,554, 63,566 (1991) (allowing voluntary inclusion on label of cautionary information not required by monograph, but not in section designated for warnings).

438. As explained above, FDA requires substantiation and categorization of risks in prescription drug labeling. See *supra* notes 146-168 and accompanying text.

439. When it approved a new prescription drug for the treatment of insomnia, FDA rejected the manufacturer's request, which was apparently based on fears of tort liability, that its use be contraindicated during pregnancy. See F-D-C REPORTS ("The Pink Sheet"), Dec. 21, 1992, at 3. Similarly, in discussions concerning the labeling of transdermal nicotine patches, manufacturers sought to include a stringent pregnancy warning concerning the teratogenicity of nicotine, but FDA opted for a milder warning evidently because it did not want to discourage women who would otherwise have smoked during their pregnancy from attempting a cessation program using a patch. See F-D-C REPORTS ("The Pink Sheet"), July 20, 1992, at 9. The Agency also has directed manufacturers to remove contraindications from existing labeling after concluding that there was insufficient data to justify a particular contraindication. See F-D-C REPORTS ("The Pink Sheet"), May 24, 1993, at T&G-1.



labeling. As a result, only marketing pressures and practical constraints will counterbalance the liability system's incentive to overwarn.

## B. *Consequences of Overwarning*

Indiscriminate and cumulative warnings about trivial risks are counterproductive. Consumers either will begin to ignore product labels altogether, thereby missing other important information, or they will become alarmed by data that were judged insufficient to warrant any more direct attempts to curtail use.<sup>440</sup> These twin evils of dilution and overreaction counsel against the use of product labeling to convey trivial risk information to consumers.

### 1. *Dilution of Existing Warnings*

There is a danger that the addition of warning statements to labeling may distract consumers' attention from existing warnings about more serious risks as well as other important information. FDA has acknowledged the problems of information overload and dilution of warnings in a number of different contexts. For these reasons, the Agency recently rejected suggestions that food labels include explicit allergy warnings.<sup>441</sup> For similar reasons, FDA dropped its proposal to require a warning about the color additive Yellow No. 5 in the labeling of OTC drugs in favor of a simple ingredient disclosure statement.<sup>442</sup> In promulgating its general labeling conditions for OTC drugs, FDA recognized that "if labeling contains too many required statements . . . the impact of all warning statements will be reduced."<sup>443</sup> As explained above, however, the Agency does not always abide by these commendable principles.<sup>444</sup>

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440. See Paul Slovic et al., *Informing People about Risk*, in *PRODUCT LABELING*, *supra* note 171, at 177-78 ("[W]e must question the value of labels warning about substances whose toxicity is far from certain (e.g., saccharin). If not ignored, such labels are likely to confuse people or raise their anxiety level, without providing much information relevant to decision making."); Henderson & Twerski, *supra* note 240, at 296.

441. See 56 Fed. Reg. 28,592, 28,615 (1991) (expressing concern that such a requirement "would overexpose consumers to warnings," and that then "consumers may ignore, and become inattentive to, all such statements"). In the final regulations, the Agency affirmed its tentative conclusion, citing comments "that an overabundance of warning statements may desensitize the general public to safety concerns and subsequently cause warning statements to lose some of their value as a means of informing the consumer about potential health hazards." 58 Fed. Reg. 2850, 2872 (1993).

442. 44 Fed. Reg. 37,212, 37,218 (1979).

443. 40 Fed. Reg. 11,717 (1975) ("In addition there is a space limitation on the number of statements that can appear on the labeling."); see also 53 Fed. Reg. 30,522, 30,530 (1988) ("The agency agrees that too many warning statements reduce the impact of important statements."); cf. 58 Fed. Reg. 46,551, 46,554 (1993) (in promulgating labeling requirement for cars equipped with air bags, the National Highway Traffic Safety Administration decided against "adding additional statements to the label because it believes that such additions would contribute to an 'information overload,' thereby diluting the impact of the most important information").

444. In considering the rule requiring pregnancy warnings for most OTC drug products, FDA reiterated its "consistent and frequently stated policy" that "warnings must be used judiciously so that they do not lose their effectiveness." 47 Fed. Reg. 54,750, 54,753 (1982). The Agency nonetheless imposed that warning requirement because it believed that "appropriate general warnings, such as this pregnancy-nursing warning,

Congress itself recognized that the overuse of warnings could distract consumer attention from label information about serious risks. When it enacted the Federal Hazardous Substances Labeling Act in 1960,<sup>445</sup> Congress provided the following reasons for limiting the Act's warning requirements only to "substantial" hazards:

If labeling were required to caution against the risk of even the most trifling indisposition, there would hardly be any substance going into the household which would not have to bear cautionary labeling, so that consumers would tend more and more to disregard label warnings, thus inviting indifference to cautionary statements on packages of substances presenting a real hazard of substantial injury or illness.<sup>446</sup>

Subsequently enacted congressional warning requirements for tobacco products and alcoholic beverages generally adhere to this policy of alerting consumers only to substantial risks, but statutory labeling requirements for saccharin and ozone depleting substances are somewhat more suspect in this regard.

Some courts also have recognized that overwarning may reduce the effectiveness of warnings about serious risks.<sup>447</sup> For instance, the United States Court of Appeals for the Fourth Circuit noted that, "[i]f pharmaceutical companies were required to warn of every suspected risk that could *possibly* attend the use of a drug, the consuming public would be so barraged with warnings that it would undermine the effectiveness of these warnings . . . ."<sup>448</sup> Physicians would not be immune to the consequences of overwarning of prescription drug risks.<sup>449</sup> In the event that labeling included warnings of all

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are an important means of educating the public about drug use." *Id.* at 54,754. FDA asserted that growing familiarity with the general warning, rather than causing consumers to tune out, would allow consumers to "more readily understand the significance of specific warnings that describe demonstrated risks of particular drugs to pregnant and nursing women." *Id.* This argument assumes, of course, that use of the boilerplate warning will not diminish the likelihood that consumers will read and attend to more specific directions and warnings. The Agency then tacked on another pregnancy warning, this one focusing on risks encountered in the third trimester, for OTC products containing aspirin. 21 C.F.R. § 201.63(e) (1993). FDA rejected comments urging that the warnings be consolidated to minimize the problems of dilution. 55 Fed. Reg. 27,776, 27,777-78 (1990).

445. See *supra* note 11.

446. H.R. REP. NO. 1861, 86th Cong., 2d Sess. (1960), reprinted in 1960 U.S.C.C.A.N. 2833, 2837.

447. See *Cotton v. Buckeye Gas Products Co.*, 840 F.2d 935, 938 (D.C. Cir. 1988) ("The inclusion of each extra item dilutes the punch of every other item. Given short attention spans, items crowd each other out; they get lost in the fine print."); *Mountain v. Procter & Gamble Co.*, 312 F. Supp. 534, 537 (E.D. Wis. 1970) (noting that to require warning of rare allergic reactions would "make such warnings less effective in all cases"); *Dunn v. Lederle Lab.*, 328 N.W.2d 576, 580 (Mich. Ct. App. 1982).

448. *Doe v. Miles Lab., Inc.*, 927 F.2d 187, 194 (4th Cir. 1991); see also *Edmondson v. International Playtex, Inc.*, 678 F. Supp. 1571, 1574-75 (N.D. Ga. 1987).

449. The California Supreme Court has observed that, "if every report of a possible risk, no matter how speculative, conjectural, or tentative, imposed an affirmative duty to give some warning, a manufacturer would be required to inundate physicians indiscriminately with notice of any and every hint of danger, thereby inevitably diluting the force of any specific warning given." *Finn v. G.D. Searle & Co.*, 677 P.2d

possible side effects, the cacophony of risk information could undermine a doctor's ability to appreciate warnings about meaningful hazards.<sup>450</sup> Such an outcome, while it may serve to insulate companies from the risk of lawsuits, ultimately would be counterproductive to patient health.

Several commentators also have voiced concerns about information overload, noting that the proliferation of hazard statements could drown out other more important information on product labels and foster public cynicism about warning statements generally.<sup>451</sup> If consumers are exposed to numerous vivid accounts of minor health threats, their attention will be diverted, their priorities will be confused, and their responsiveness to important messages will be decreased. Whatever their degree of sophistication, consumers can attend only to a limited number of information signals in a given period of time. Thus, an initial draft of the *Restatement (Third) of the Law of Torts* includes the following important comment:

Courts should be cautious to avoid imposing a duty to provide overly numerous or too detailed warnings. Such warnings are likely to be ignored and thus ineffective. . . . Useful instructions and warnings call the user's attention to dangers that can be avoided by careful product use, but they can be debased if attention must also be directed to trivial or far-fetched risks. Should courts require inappropriately elaborate warnings, consumers would be disadvantaged.<sup>452</sup>

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1147, 1153 (Cal. 1984) ("Knowledge of a potential side effect which is based on a single isolated report of a possible link between a prescription drug and an injury may not require a warning."); see also *Thomas v. Hoffman-LaRoche*, 949 F.2d 806, 816 n.40 (5th Cir.) (noting that imposition of liability for failure to warn about reported but unconfirmed adverse experiences with prescription medications could "force drug manufacturers to list, and perhaps contraindicate, every possible risk in order to avoid the possibility of liability"), *cert. denied*, 112 S. Ct. 2304 (1992).

450. See *Thomas*, 949 F.2d at 816 n.40 ("If manufacturers so respond to the possibility of liability, physicians will begin to ignore or discount the warnings provided by the drug manufacturers. Permitting a jury to find liability on such a basis would undermine the important role of warnings as a device to communicate vital information to physicians.").

451. See, e.g., *Beales*, *supra* note 404, at 250 ("[A]dditional label information may reduce the probability that consumers read, note, and act upon other information on the label."); Schwartz & Driver, *supra* note 418, at 59-60 ("A product user who recognizes that one of the hazards addressed in a warning is trivial is likely to discount the importance of the other hazards addressed in the warning. . . . If every possible danger in life were accompanied by a warning, product users quickly would become inured to all warnings, and eventually would ignore them." (footnote omitted)). But see Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795, 1831 (1989) (discounting these concerns by asserting that "people already handle substantial amounts of complex information").

452. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. f (Tentative Draft No. 1, 1994), at 24-25; see also *Beales*, *supra* note 404, at 251 ("Ubiquitous disclosure that a product may be hazardous, although probably true, is likely to rob that statement of its information value."); Henderson & Twerski, *supra* note 240, at 296 ("Courts should recognize that warning about relatively remote risks generates substantial social costs which in most cases outweigh any corresponding benefits in reducing accident costs."); Schwartz & Driver, *supra* note 418, at 54 n.71 ("The net effect of such a warning may be the prevention of fewer accidents than a warning that addressed only the three most important hazards.").

If warnings about relatively trivial risks are given equal prominence with warnings about more significant problems, people will be unable to distinguish what is important from what is unimportant.<sup>453</sup> If warnings of all sort proliferate, the general public may become bored or cynical and cease to pay attention altogether.<sup>454</sup>

Apart from the possibility that consumers simply will stop paying attention, warnings about every possible risk associated with a product could confuse the public. For instance, certain consumers may believe that a product whose label discloses several small risks is more hazardous than a product whose label warns of a single serious risk.<sup>455</sup> Conversely, one study found the perverse effect that consumers viewed products with warning labels as more desirable than those without them, perhaps because products accompanied by warnings were perceived as containing more powerful ingredients.<sup>456</sup> One quite serious possibility is that overwarning will distract consumers from attending to the directions for proper use, thereby increasing the chance of injuries resulting from product misuse.<sup>457</sup> Such inappropriate responses to risk labeling may outweigh the anticipated benefits of warning efforts, particularly when the primary purpose of such efforts is nothing more than fulfilling an amorphous "right to know."

The problem of information overload is compounded when consumers are given raw data without straightforward guidance about how to respond. During proceedings on Proposition 65, FDA Commissioner Frank Young explained the Agency's opposition to indiscriminate warnings about potential carcinogens.

We are greatly concerned that a requirement for placing warning labels on all such products will lead to consumer confusion and actually diminish the effect of the labeling that is now required. . . .

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453. See Lehto & Miller, *supra* note 400, at 233 ("[P]resenting a long list of messages with a warning label could be quite counterproductive. This problem would be most serious when messages vary extensively in importance, since processing the less relevant messages may consume the limited mental resources and time that should be allotted to the important messages."); Henderson & Twerski, *supra* note 240, at 308 ("Sequencing [of warnings in labeling] inevitably denotes relative importance and will have an impact on the weight a consumer attaches to the risk.").

454. See Viscusi, *supra* note 187, at 162 ("If everything in society is stamped 'Hazardous,' then in effect no warnings will be given. The overall task . . . is to be selective and to earmark those products that merit warnings . . ."); Yesley, *supra* note 363, at 316 ("Increased familiarity with warnings as a result of their growing number may breed disregard, if not contempt. Individual warnings, no matter how well designed, will lose their saliency in a forest of other warnings.").

455. See Kanouse & Hayes-Roth, *supra* note 373, at 156; Slovic et al., *supra* note 440, at 177.

456. Michael Ursic, Research Note, *The Impact of Safety Warnings on Perception and Memory*, 26 HUMAN FACTORS 677, 680-81 (1984).

457. See Viscusi, *supra* note 187, at 147 (noting that, because "the major risks of pesticide products are from misuse . . . rather than inadequate precautions during proper use, excessive risk information may actually increase the overall risk posed by the product."); see also *Liesener v. Weslo, Inc.*, 775 F. Supp. 857, 861 (D. Md. 1991) (recognizing "the need to keep warnings simple and succinct enough to be readable and effective; the more detailed, the less chance there is that they will be read at all, thereby perversely increasing the risk of injury instead of lessening it.").

Messagings warning of product ingredients that actually pose no risk will prompt consumers not to read labeling at all. Indeed, for products that now contain necessary warning labels, those warnings might be overlooked entirely, to the detriment of those citizens for which they were intended.<sup>458</sup>

Unfortunately, the task of selecting and appropriately highlighting only the most serious hazards for inclusion in labeling cannot be accomplished so long as federal agencies must vie with state lawmakers and the courts for control over risk communication decisions.

## 2. *Overreaction to Additional Warnings*

Even if consumers do pay attention to warnings, they may well overreact to the information, particularly when the warning statement is intended to convey a subtle message about low probability risks.<sup>459</sup> Such an overreaction is especially likely in the case of warnings about statistically remote risks of dreaded diseases such as cancer. Thus, when it imposed the CFC warning requirement for consumer products, FDA rejected a comment urging that the warning make specific reference to skin cancer effects.

The public is, understandably, exceptionally alarmed by risks of cancer. A reference to a cancer risk on the label should be accompanied by a careful explanation which may require a lengthy text. Furthermore, a reference specifically to cancer, even though stated to be an environmental effect, could without further explanation lead some consumers to believe the risk is greater for the individual user of the product.<sup>460</sup>

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458. Frank E. Young, M.D., Statement before the Science Advisory Board of the California Health and Welfare Agency (Dec. 11, 1987), at 16 (on file with the author). *But see* Note, *Proposition 65's Right-To-Know Provision*, *supra* note 227, at 704-05 ("In any event, some degree of overwarning may be an acceptable side effect . . . . If having 'too many' warnings is the only way to avoid requiring citizens to discover for themselves the hazards of a particular chemical, this may be a worthwhile tradeoff.").

459. *See* Viscusi, *supra* note 358, at 287-88 ("Perhaps the major danger from any risk-communication effort is that instead of informing people these programs will serve to unduly alarm them and cause an overreaction to the risk information."); Richard J. Zeckhauser & W. Kip Viscusi, *Risk Within Reason*, 248 *SCIENCE* 559 (1990).

460. 42 Fed. Reg. 22,019, 22,026 (1977); *see also* John Higginson, *Everything Is a Carcinogen?*, 7 *REG. TOXICOL. & PHARMACOL.* 89, 93 (1987) ("[S]uch misconceptions are dangerous since the public may tend to regard all potential carcinogenic stimuli as equally important irrespective of dose and mechanism and equate the trivial with the significant.").

The CFC warning therefore only cautions that a product "[c]ontains a chlorofluorocarbon that may harm the public health and environment by reducing ozone in the upper atmosphere."<sup>461</sup>

In fact, there is no distinctive individual risk from use of products containing CFCs, but there may be direct health risks associated with alternative propellants. Although FDA was careful not to mention cancer in the warning statement, it failed to consider the potential adverse health effects that could arise if consumers reacted to the somewhat less threatening warning by switching to products containing non-CFC propellants. The primary purpose of the CFC warning was to encourage use of alternative propellants, though several comments pointed out these alternatives caused adverse effects such as eye irritation and raised flammability concerns. FDA, however, responded that "[t]he present action relates only to the adverse effects of [CFCs] upon stratospheric ozone, and the potential physiological hazards from other products are not within the scope of this regulation."<sup>462</sup> FDA did take into consideration the availability of safe alternative delivery systems for purposes of deciding whether a particular use would be exempted as "essential,"<sup>463</sup> and CPSC addressed a similar objection to its identical CFC warning by pointing out that the labeling requirement would not prevent consumers from purchasing products containing CFCs if they were thought to be safer than alternatives.<sup>464</sup> Even so, the possibility that warnings about CFC propellants could lead to the use of alternatives posing a greater personal risk for users (albeit less of an environmental concern) did not lead either Agency to reconsider the desirability of the proposed warnings.

Requiring warning statements about unsubstantiated or insignificant risks in the labeling of useful products can distort consumer choices. "Warnings may not take into account the benefits that are gained from using a product . . . includ[ing] both the positive advantages afforded by the product and also the avoidance of costs that would result from not using the product."<sup>465</sup> For

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461. E.g., 21 C.F.R. § 801.425(a) (1993) (medical devices).

462. 42 Fed. Reg. 22,019, 22,027 (1977). Yet FDA has recognized that hydrocarbon propellants are subject to abuse, 21 C.F.R. § 740.11(b)(1) (1993), and that the sniffing of fumes by youngsters has become a serious problem. See Laura Sessions Stepp, *Sniffing Fumes: A Growing and Deadly Trend Among Teenagers*, WASH. POST, Jan. 30, 1994, at A1. These CFC alternatives are also flammable. *Nowak v. Fabergé U.S.A., Inc.*, 812 F. Supp. 492, 495 (M.D. Pa. 1992). Use of alternative propellants recently resulted in widely publicized recalls because of health problems. See 41 MORB. & MORT. WEEKLY REP. 965, 966 (1993); *Two Are Hospitalized, 41 Become Ill After Using a New Spray Product*, WASH. POST, Dec. 28, 1992, at A7 (leather protectant spray using petroleum distillates instead of CFCs). (Indeed, CPSC mandates special labeling for products containing petroleum distillates because it regards them as especially hazardous. 16 C.F.R. § 1500.14(b)(3)(i) (1993).)

463. 42 Fed. Reg. 22,019, 22,027-28 (1977).

464. 42 Fed. Reg. 42,780, 42,782 (1977).

465. Yesley, *supra* note 363, at 316; see also Schwartz & Driver, *supra* note 418, at 39 n.4 ("Warnings which raise fears in the minds of potential consumers out of proportion to the actual risks involved . . . may cause consumers to forego use of a socially beneficial product."). By contrast, before a product label may highlight health benefits, FDA demands that there be no undisclosed potential increases in other risk factors.

instance, many food products contain potentially carcinogenic nitrites, but at present these preservatives provide one of the best means available for protecting against lethal food poisoning.<sup>466</sup> In addition, the public should be more concerned with maintaining a healthy diet than with warnings about possible low-level carcinogens in food products.<sup>467</sup> Absent consistent and differentiated cautionary statements allowing comparisons among the risks posed by different products, narrowly focused warning requirements may distort these trade-offs.

CPSC may impose labeling requirements only if there is substantial evidence that a warning is "reasonably necessary" to prevent or reduce unreasonable risks of injury.<sup>468</sup> In applying this standard, reviewing courts have balanced the identifiable advantages of a warning requirement against possible disadvantages such as consumer overreaction. In setting aside a CPSC regulation that required warning signs on new pool slides, one court found that the explicit mention of the risk of paralysis "might unnecessarily frighten away those who would be willing to buy them if they knew how remote the risk actually was."<sup>469</sup> The concern with frightening consumers was not related to any potential health benefits foregone by not using pool slides, or risks associated with alternatives, but rather to the potential economic harms visited upon manufacturers of products that are made to appear overly hazardous. If CPSC must take such considerations into account before imposing a warning label requirement, other agencies should at least give some thought to the possible health hazards that may arise from discouraging the use of relatively safe products.

FDA did exempt essential uses from the CFC warning requirement and, in commenting on EPA's ozone depleting substances regulations, cautioned against requiring warnings on essential products for fear that patients would be unduly alarmed and discontinue important therapies.<sup>470</sup> Likewise, in the case

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See, e.g., 21 C.F.R. § 101.14(e)(3) (1993) (prohibiting health claims in the labeling of food products that contain "disqualifying levels" of undesirable nutrients).

466. See Cooper, *supra* note 171, at 302.

467. See David McCallum, *Risk Factors for Cardiovascular Disease: Cholesterol, Salt, and High Blood Pressure*, in RISK COMMUNICATION 67, 69 (J. Clarence Davies et al. eds., 1987) (Risk communication "campaigns must recognize overall nutrition and the interaction of dietary factors. (For example, not drinking milk to avoid fat rather than drinking low-fat milk can lead to calcium deficiencies.)"). See generally NRC, DIET AND HEALTH: IMPLICATIONS FOR REDUCING CHRONIC DISEASE RISK (1989).

468. 15 U.S.C. § 2056(a) (1988); see also 58 Fed. Reg. 8013, 8015 (1993) (withdrawing proposal to require that toys with small parts warn of the hazard of choking because CPSC could not find that expected benefits of such requirement "would bear a reasonable relationship to its costs").

469. Aqua Slide 'N' Dive Corp. v. CPSC, 569 F.2d 831, 844 (5th Cir. 1978); cf. Southland Mower Co. v. CPSC, 619 F.2d 499, 522 (5th Cir. 1980) (finding that lawn mower label was "not shocking or gruesomely explicit and would not pose an unwarranted deterrent to potential purchasers").

470. See *supra* notes 80 & 211 and accompanying text. For similar reasons, one court rejected a plaintiff's argument that the warning "ought to be so strong, regardless of medical experience, as to frighten people from receiving the beneficial aspects of the [vaccination] program." *Boruski v. United States*, 803 F.2d 1421, 1427 (7th Cir. 1986).

of OTC drugs, FDA has demonstrated a similar concern about not unduly alarming consumers who would otherwise greatly benefit from use of such products.<sup>471</sup> For example, in proposing labeling for sunscreen products, the Agency rejected a suggestion that consumers be alerted to the risk that the continuous use of sunscreens may suppress cutaneous vitamin D<sub>3</sub> synthesis because it found that most persons obtain adequate amounts of vitamin D in their diet, and "because such a warning might discourage the use of sunscreens, especially in children."<sup>472</sup> Regulators and courts therefore should take into account the consequences that may arise if a warning effort, intentionally or not, persuades some consumers to refrain from using a product and either to forego the benefits of use or to switch to alternatives that may be more hazardous.

The use of warnings may have other unintended effects on consumer behavior. Some have argued in favor of requiring specific warnings of the addictive properties of products such as alcohol, cigarettes, and certain drugs.<sup>473</sup> FDA does require that potentially addictive medications bear the statement "Warning—May be habit forming."<sup>474</sup> Some have suggested, however, that such warnings could be counterproductive.

The warning would frighten away many people who are unlikely to become addicted . . . [while] people with a propensity to engage in nonconforming or thrill-seeking behavior would be more likely to use the product in consequence of the warning; they will take a warning as a dare or regard products with warnings as more alluring to them just in virtue of their having been identified as risky. . . . [T]o label a product "addictive" may convey the impression that consumption will be intensely pleasurable, at least for a time.<sup>475</sup>

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471. See, e.g., 55 Fed. Reg. 27,776, 27,782 (1990) ("[T]he agency is concerned that a reference to bleeding as included in the proposed [third-trimester pregnancy] warning may discourage compliance with medically supervised uses of aspirin, e.g., the treatment of chronic arthritis, and therefore is not including a specific reference to bleeding in the new warning for these OTC drug products."); 44 Fed. Reg. 59,509, 59,514 (1979) (suggesting that Congress' failure to extend saccharin warning to other products such as toothpastes may reflect recognition of health benefits that result from encouraging use by improving palatability).

472. 58 Fed. Reg. 28,194, 28,243 (1993) (but inviting further comments on whether the elderly, who are more prone to vitamin D deficiency, should be alerted to this possibility). By contrast, the Agency rejected the argument that an "Avoid contact with eyes" warning should be deleted because it might discourage consumers from applying sunscreens to their faces where it is most needed. *Id.* at 28,241.

473. See, e.g., Donald W. Garner, *Cigarette Dependency and Civil Liability: A Modest Proposal*, 53 S. CAL. L. REV. 1423 (1980). A few courts have found manufacturers liable for failing to warn of a product's addictive qualities. See *Marsee v. United States Tobacco Co.*, 639 F. Supp. 466, 471 (W.D. Okl. 1986) (smokeless tobacco), *aff'd*, 866 F.2d 319 (10th Cir. 1989); *Crocker v. Winthrop Lab.*, 514 S.W.2d 429, 432-33 (Tex. 1974) (prescription analgesic represented as non-addicting).

474. 21 U.S.C. § 352(d) (1988); 21 C.F.R. § 329.10(c) (1993).

475. Alan Schwartz, *Views of Addiction and the Duty to Warn*, 75 VA. L. REV. 509, 556-57 (1989) (also noting that "requiring the minimal warning could discourage attempts by addicts to change their lives").



Similarly, label warnings of risks other than addiction may encourage rather than deter hazardous behavior.<sup>476</sup> In proposing a warning requirement for products in self-pressurized containers, FDA recognized that an intentional misuse warning “could lead those persons who might wish to inhale intoxicating substances directly to products that could be abused.”<sup>477</sup> FDA dismissed this concern, however, by noting that “[n]o warning can protect from harm those who intentionally indulge in practices that they know to be harmful.”<sup>478</sup>

Other secondary effects of warnings include the possibility of “indirect psychological costs of risk labeling, such as suggesting to people symptoms that they would not otherwise have, or imposing additional health-threatening stress, loss of self-esteem, etc., for people who keep smoking even though the label tells them it is foolish.”<sup>479</sup> In proposing its monograph for OTC stimulant drug products, FDA recognized the “possibility that some consumers might develop psychosomatic side effects” after reading about risks, but it rejected this concern without any detailed explanation.<sup>480</sup> The same argument was made with regard to PPIs for prescription drugs, but FDA discounted this possibility and explained that the positive effects of supplying information about potential adverse reactions would offset any possible negative effects:

Accurate expectations may help reduce uncertainty and anxiety about possible effects of treatment. The patient may also be better able to interpret and identify more accurately the cause of drug-induced reactions, and treatment decisions will accordingly be based on more precise information.<sup>481</sup>

Although admittedly speculative, the possibility of unintended secondary effects such as encouraging risky behavior or suggesting side effects should caution

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476. See McGuire, *supra* note 373, at 109-10 (“For example, among young people (and especially young males), warning labels about the risk involved in pharmaceuticals, cigarettes, alcohol, driving styles, certain sporting equipment and practices, etc., may actually have a net positive incentive power, drawing the person to the practice (especially in public situations) rather than being a deterrent.”).

477. 38 Fed. Reg. 6191 (1973).

478. *Id.* In the preamble to its final rule, FDA mentioned that one comment was received from “a former addict [who] stated his belief that while most persons would ignore the warning, some would not, and to that extent the warning would be worthwhile.” 40 Fed. Reg. 8912, 8915 (1975).

479. Beales, *supra* note 404, at 243, 258-59 (statement of William McGuire).

480. 43 Fed. Reg. 25,544, 25,562 (1978). *But cf.* 21 C.F.R. § 7.50 (1993) (“[FDA] will intentionally delay public notification of recalls of certain drugs and devices where the agency determines that public notification may cause unnecessary and harmful anxiety in patients and that initial consultation between patients and their physicians is essential.”). Suggestion-induced illnesses are a documented phenomenon. *See, e.g.*, Larry S. Goldman, Book Review, 327 NEW ENG. J. MED. 1764 (1992) (reviewing ROBERT KELLNER, PSYCHOSOMATIC SYNDROMES AND SOMATIC SYMPTOMS (1991)); 39 MORB. & MORT. WEEKLY REP. 301 (1990) (CDC analysis of reports of food poisoning in children attending day-care center, concluding that it represented a “mass sociogenic illness”).

481. 42 Fed. Reg. 37,636, 37,639 (1977) (estrogen PPI); *see also* 44 Fed. Reg. 40,016, 40,023 (1979) (“The agency does not believe that patient labeling will significantly increase the incidence of suggestion-induced side effects.”).

against too ready a reliance on warnings that fulfill nothing more than the "right to know."

The risk of overreaction is not limited to lay consumers. Physicians are vulnerable as well. Overwarning of prescription drug side effects may adversely affect prescribing decisions.

[FDA] has an interest in "rational prescribing," *i.e.*, ensuring that the risks and benefits of a particular drug be fairly presented so that a physician can compare them with other available therapies. That goal is not advanced if a drug is made to appear riskier than other drugs and other therapies due to the over-dramatization of risk information. To allow a warning based on inconclusive evidence or scientific hunches results in doctors not prescribing effective drugs to a patient because of the erroneous belief that a side-effect might occur.<sup>482</sup>

As explained in the previous section, giving undue prominence to trivial or unsubstantiated risks will draw attention away from more serious risks. FDA therefore requires the substantiation and appropriate categorization of risks in prescription drug labeling.<sup>483</sup>

FDA's efforts to convey accurate and balanced risk information are undermined when courts entertain failure-to-warn claims in these cases. Even if physicians are not misled by warnings about trivial risks, they may nonetheless avoid using perfectly safe and effective therapeutic agents for fear of malpractice liability if they disregard a warning.<sup>484</sup> Indeed, if phrased as a contraindication, precautionary information would effectively amount to a direction to the physician never to use the drug in those circumstances. Patients will be the ultimate losers of excessive and misguided warning efforts undertaken by manufacturers in response to adverse judgments in products liability cases. There is a danger, then, that physicians may alter their prescribing decisions in response to warnings about trivial drug risks, either by taking all warnings less seriously or taking trivial warnings too seriously. As explained

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482. *Feldman v. Lederle Laboratories*, 592 A.2d 1176, 1200 (N.J. 1991) (Garibaldi, J., dissenting), *cert. denied*, 112 S. Ct. 3027 (1992); *see also* Cooper, *supra* note 334, at 238 ("This point has additional force where there is no similar collection of risk information about alternative therapies, such as surgical procedures."); Scarlett, *supra* note 163, at 36 ("[O]verstated warnings could tip the judgment of the medical profession in an undesirable direction.").

483. *See supra* notes 146-168 and accompanying text.

484. *See* *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 887 (Minn. 1970) (deviation from manufacturer's recommendation provides prima facie evidence of negligence); *Julien v. Barker*, 272 P.2d 718, 724 (Idaho 1954) (package inserts provide "prima facie proof of a proper method of use"); James R. Bird, Note, *Package Inserts for Prescription Drugs as Evidence in Medical Malpractice Suits*, 44 U. CHI. L. REV. 398 (1977); *cf.* *Ramon v. Farr*, 770 P.2d 131, 134-35 (Utah 1989) (declining to follow *Mulder* but conceding that the package insert provides some evidence of the standard of care); 40 Fed. Reg. 28,582, 28,585 (1975) (according to FDA, physicians should feel free to deviate from the package insert).

above, consumer choices about using other products may be distorted for similar reasons.

### C. *Alternatives to Warning Labels*

Thus, there are several cogent reasons for using label warnings on consumer products sparingly and relying instead on other means to convey hazard information. The dual concerns with dilution and overreaction are especially relevant where a warning is intended only to disclose information rather than to ensure safe use of a product. In particular, if public disclosure of inconclusive animal data is the goal, risk labeling is not the appropriate mechanism. Such warnings are likely to be ignored, distract users from other more important information on the label, cause unnecessary alarm, or mislead consumers into believing that a product poses a risk distinct from that posed by other products containing similar ingredients. If the goal is simply to advance a public dialogue, there are better means available.

In the case of extremely low-level risks, for example, it may not be possible to include hazard information on a product label that accurately conveys the true extent of the risk to consumers. Because persons tend to greatly overestimate the likelihood of low probability events,<sup>485</sup> the placement of any cautionary information whatsoever in product labeling is likely to overstate the true risk. The best response to such problems may be to forego the use of warnings altogether,<sup>486</sup> as FDA has done in the case of food products. If warnings are required, consumers should be given information that allows a comparison of risks posed by different products serving the same purpose as well as information concerning benefits that may be foregone in choosing not to use a particular product.<sup>487</sup> As a practical matter, the difficulty of providing complete and balanced information in product labeling suggests that warnings about insignificant risks should not be included in labeling.

The many shortcomings of warning labels do not mean that risk communication efforts should be abandoned altogether for low-level product risks such as potential allergens or chronic health hazards. Instead, other methods for conveying relevant information should be explored. Such methods range from less alarming label statements, such as ingredient disclosures, to

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485. See *supra* note 459.

486. See Cooper, *supra* note 171, at 301-02 ("If the risk is not serious enough to warrant a ban, it probably also does not warrant a warning on a large number of products.").

487. See NAS, *supra* note 368, at 33 (Consumers "choose between options, each of which presents some risks. Each also presents benefits . . . Both kinds of knowledge are needed for an informed choice."); Aaron D. Twerski et al., *The Use and Abuse of Warnings in Products Liability—Design Defect Litigation Comes of Age*, 61 CORN. L. REV. 495, 503 (1976) ("If, as a result of an adequate warning, consumers will be faced with alternatives that are even more dangerous than the questioned product without a warning, then perhaps that warning should not be imposed or if imposed should be couched in less frightening language."); Kanouse & Hayes-Roth, *supra* note 373, at 157.

public education campaigns. Certain of these alternatives would be more effective and more closely commensurate with the level of attention warranted by the evidence with respect to low-level product risks. The means chosen for public disclosure should convey what is known about the health effects of products in an accurate, comprehensive, and balanced fashion. If a risk is serious enough to merit identification by a warning label, however, more direct forms of regulation may be superior.

### 1. *Less Alarming Disclosures in Labeling*

Labeling statements short of warnings can be used to provide cautionary information in some instances. For example, mandatory disclosures of the presence of a certain ingredient can provide allergic persons with the information that they need to avoid certain products without unnecessarily alarming the great majority of consumers. As FDA explained:

[I]f notification of the presence of FD&C Yellow No. 5 can be satisfactorily achieved by means other than a warning statement on the labels of drug products, such other means should be used because of space limitations and the importance of reserving the use of warning statements to situations involving a greater potential for adverse reaction or potential safety hazard.<sup>488</sup>

The Agency therefore generally has rejected suggestions that product labels include warnings about possible allergens.<sup>489</sup> Ingredient declarations in these cases can satisfy the disclosure function without overwhelming consumers with risk information. In addition, mandatory disclosures that specify the amount of an ingredient present in a serving or dose of a product may suffice where excessive consumption of a common substance (for example, sodium) is widely understood as contributing to a certain health problem (for example, hypertension).<sup>490</sup> In such cases, quantitative ingredient information allows consumers to compare products and monitor their total intake if necessary.

Ingredient disclosures cannot, however, provide meaningful information to persons who do not know whether they are allergic to the substance, and quantitative declarations will not succeed unless consumers understand that the ingredient poses some risk. Thus, FDA opted for a CFC warning instead of the ingredient disclosure requirement adopted by EPA because "consumers may

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488. 44 Fed. Reg. 37,212, 37,218 (1979).

489. See *supra* note 100.

490. See 21 U.S.C.A. § 343(q)(1)(D) (West Supp. 1993); 21 C.F.R. § 101.9(c)(8)(i) (1993). FDA's sodium labeling proposal for OTC drug products would include an ingredient disclosure but would also require a warning at higher levels. See *supra* note 142.

not understand the significance of a presence of chlorofluorocarbon in a product, and the hazard posed, from a statement that simply states that the product contains chlorofluorocarbon.”<sup>491</sup> Indeed, “[s]ome consumers may assume the statement is made to indicate an especially valuable ingredient, and they may interpret the statement as a reason for purchasing the product.”<sup>492</sup> Unless consumers first are educated about the risks associated with an ingredient, simple disclosure statements will be ineffective and possibly even counterproductive.

There may, however, be still other ways to provide risk information in product labeling without using warning statements. Unlike cautionary statements about acute hazards that seek to encourage particular types of behavior in the use of the product, disclosures of risk information that do nothing more than fulfill a right to know and possibly affect the purchase decision need not appear as warnings. It may make more sense to develop a uniform coding system that could be applied to labels of diverse products for purposes of disclosing basic risk information. Somewhat like the five alphabetical pregnancy categories used by FDA as a shorthand to describe the teratogenicity of prescription drugs,<sup>493</sup> a chronic risk code could be developed for consumer products.<sup>494</sup> Risk averse persons who are sufficiently interested in pursuing further information would be able to do so. In addition, unlike Proposition 65, which indiscriminately labels substances as known carcinogens whether the lifetime risk of cancer is one-in-ten or one-in-100,000, a uniform coding system could differentiate (even if only imprecisely) between the varying degrees of risk posed by different products.

Some commentators have suggested using numerical scales to convey risk information.<sup>495</sup> One such proposal would use a compressed logarithmic scale

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491. 42 Fed. Reg. 22,019, 22,020 (1977).

492. *Id.* FDA recently suggested requiring that the labeling of toothpaste products include information about their fluoride levels. 57 Fed. Reg. 55,199 (1992). By allowing consumers to select toothpastes with lower levels of fluoride, FDA hoped to minimize the risk of fluorosis (discoloration of teeth). Initial comments from the industry argued that consumers might overreact and decrease use of fluoride toothpastes, thereby increasing the risk of dental caries. *Id.* at 55,200. Subsequent comments, based on consumer surveys, argued just the opposite, namely that individuals believe fluoride is good and would select toothpastes containing the highest levels of this ingredient. F-D-C REPORTS (“The Rose Sheet”), April 5, 1993, at 3. It was precisely for such reasons that FDA prohibited any reference to fluoride in the labeling of prenatal vitamin products, 21 C.F.R. § 250.10(b) (1993), or a description of the level of fluoride present in bottled water. 58 Fed. Reg. 2302, 2314 (1993).

493. See 21 C.F.R. § 201.57(f)(6)(i) (1993), discussed *supra* notes 165-168 and accompanying text. In addition, the labeling of controlled substances must bear a symbol displaying the schedule applicable to the narcotic drug (a roman numeral adjacent to or within the letter “C”). See 21 U.S.C. § 825(a) (1988); 21 C.F.R. § 1302.03 (1993).

494. The State of California apparently is considering proposals to use a single chronic hazard symbol for products subject to the Proposition 65 warning requirement. See F-D-C REPORTS (“The Rose Sheet”), Feb. 15, 1993, at 14; FOOD CHEM. NEWS, Feb. 1, 1993, at 77. Some of the limitations in using symbols are discussed in *supra* note 400.

495. See, e.g., HADDEN, *supra* note 378, at 245-48 (describing scaling system for rating the relative hazards posed by a product); Ernest Newbrun, *Criteria of Cariogenicity for Labeling Foods*, 105 J. AM. DENTAL ASS’N 627 (1982) (suggesting that, instead of possible warning statement, food labels use numerical

to denote the annual risk of mortality posed by a product or activity, with larger numbers reflecting greater safety margins.<sup>496</sup> Under this system, a product posing a one-in-ten annual risk of death would be designated as 1.0, while a product posing a one-in-one million annual risk of death would be designated as 6.0. If one applied existing risk estimates, approximate risk scaling for some of the products discussed in the previous parts of this Article might be as follows: cigarettes (2.8), oral contraceptives (4.4), tampons (5.0), and saccharin-containing soft drinks (5.2). A product just over the Proposition 65 threshold would be assigned a 6.8 on this scale.

The shortcomings of the underlying risk assessments (or the complete lack of reliable estimates for many products) would make accurate and uniform risk scaling impossible. The proponents of this approach also concede that consumers' lack of familiarity would represent a serious initial hurdle for their proposal, but they argue that public comprehension will develop over time, just as happened with use of the Richter Scale for measuring earthquake intensity.<sup>497</sup> The authors may, however, be overestimating the extent to which lay persons recognize that the Richter Scale is logarithmic rather than linear, and efforts to use a common risk metric may be misleading when very different products or activities are compared.<sup>498</sup> Nonetheless, safety scaling has undeniable benefits for presenting information about low-level or chronic risks. Without causing unnecessary alarm, it would allow interested consumers to evaluate hazards associated with competing products. Acute hazards, particularly those that can be avoided by following precautionary instructions, would still need to be spelled out in full, but such information would no longer have to compete with chronic risk information for users' attention.

## 2. *Public Education Campaigns*

Risk labeling sometimes is characterized as serving primarily educational ends, but other media could be used to convey hazard information more effectively.<sup>499</sup> The labeling alternatives discussed above would, in most cases, require accompanying efforts to educate consumers about how to interpret the information, whether that means explaining the relevance of ingredient disclosures or translating chronic risk codes or scales. Indeed, it may be wiser

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scale to rank foods based on risk they pose of tooth decay).

496. JOHN URQUHART & KLAUS HEILMANN, *RISK WATCH: THE ODDS OF LIFE* 47-48 (1984).

497. *Id.* at 193.

498. See 44 Fed. Reg. 59,509, 59,512 (1979) ("The fact that some users of hair dyes engage in dangerous sports does not entail that they are prepared to disregard even small risks from hair dyes."); NAS, *supra* note 368, at 52 ("When lay and expert values differ, reducing different kinds of hazard to a common metric (such as number of fatalities per year) and presenting comparisons only on that metric have great potential to produce misunderstanding and conflict and to engender mistrust of expertise.").

499. See *Aqua Slide 'N' Dive Corp. v. CPSC*, 569 F.2d 831, 841 (5th Cir. 1978) (suggesting use of public education campaigns).

to focus primarily on the need for public education campaigns about product risks and to rely on labeling as an adjunct to such efforts.

Congress has included public education requirements in legislation governing the labeling of products such as cigarettes and smokeless tobacco products.<sup>500</sup> Agencies have undertaken multi-media educational efforts in some cases, particularly when serious new hazards with widely-used products subsequently come to light.<sup>501</sup> Unfortunately, broader public education efforts frequently are adopted only as an afterthought to more traditional warning label requirements.

In 1978, BATF had proposed to require warning labels on alcoholic beverages concerning the risks of fetal alcohol syndrome.<sup>502</sup> The proposal was abandoned one year later, however, in favor of a public awareness campaign.<sup>503</sup> The Agency explained that it wanted to pursue other forms of education before deciding to mandate a warning label.<sup>504</sup> In addition to believing that the issue was too complex to be readily explained in labeling, the Bureau expressed concerns about overstating the risk and unnecessarily frightening women who may have had an occasional alcoholic beverage during their pregnancies.<sup>505</sup> BATF therefore announced a plan which included publishing and distributing its report, disseminating brochures to the public and medical profession, encouraging the development of educational programs in schools, preparing public service television and radio announcements, and issuing press releases.<sup>506</sup> BATF promised, however, that it would once again consider the warning label proposal if these efforts proved unsuccessful or if more precise medical

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500. See *supra* note 47 and accompanying text.

501. See, e.g., 50 Fed. Reg. 51,400, 51,401 (1985) (FDA public education campaign to alert consumers about risk of Reye syndrome when using aspirin); 47 Fed. Reg. 26,982, 26,982 (1982) (describing joint efforts of FDA, CDC, and other organizations to publicize risk of toxic shock syndrome associated with tampons, but adding that label warnings were needed to remind women of risk). In the early 1970s, USDA rejected petitions demanding that warning labels concerning the risk of salmonella appear on meat and poultry products, opting instead for consumer education programs. Cf. *American Pub. Health Ass'n v. Butz*, 511 F.2d 331, 332-35 (D.C. Cir. 1974) (holding that this choice represented proper exercise of discretion by agency). More recently, USDA decided that its longstanding educational efforts had to be supplemented by safe handling instructions in product labeling. See 58 Fed. Reg. 58,922, 58,928 (1993), discussed *supra* note 86.

502. 43 Fed. Reg. 2186 (1978).

503. 44 Fed. Reg. 8288 (1979).

504. *Id.*

505. *Id.* at 8292.

506. *Id.* at 8293; see also NAS, *supra* note 368, at 159 ("[T]he communicating organization should synthesize the scientific information base into a formal 'white paper' that can be generally released. This document should summarize relevant quantitative and qualitative scientific information, the attendant uncertainty about the risk and about risk reduction alternatives, and the assumptions employed."); Clark E. Khoury; Note, *Warning Labels May Be Hazardous to Your Health: Common-Law and Statutory Responses to Alcoholic Beverage Manufacturers' Duty to Warn*, 75 CORN. L. REV. 158, 182-83 (1989) (criticizing warning label mandated by Congress and instead recommending reliance on an "institutionally-based" educational approach); McGuire, *supra* note 373, at 107-08 (noting suggestive evidence indicates that public service advertisements "may be more cost-effective than product labels for lessening health risks").

evidence became available.<sup>507</sup> Congress intervened a decade later by mandating that certain health warnings appear on the labels of alcoholic beverages.

Public education efforts would allow for a more detailed and balanced account of equivocal animal findings than could possibly be conveyed on product labels, and the information then could be disseminated further by the lay media. For example, FDA has informed the public about adverse scientific findings through advisory committee proceedings, talk papers, press releases, and articles.<sup>508</sup> Similarly, as a number of courts have recognized, physicians can be educated about prescription drug hazards through any number of vehicles other than product labeling.<sup>509</sup> Several consumer guides to prescription drugs are readily available,<sup>510</sup> and similar reference materials could be developed for other products.<sup>511</sup> Although such compilations would reach only a fraction of the population exposed to product labeling, interested persons would be able to share in this information, instead of being confronted with meaningless or vague warning statements on product labels.

Although public education campaigns can potentially reach a greater number of persons, and can more accurately describe the nature and true extent of a risk than is possible through labeling, they also have serious limitations and should not substitute for direct forms of regulation where those are appropriate.<sup>512</sup> Amorphous calls for educational efforts to convey risk informa-

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507. 44 Fed. Reg. 8288, 8293 (1979).

508. FDA recently decided that chronic risk information about doxylamine could be discussed in an FDA CONSUMER article rather than in product labeling. 59 Fed. Reg. 4216, 4217 (1994); *see also* NAS, *supra* note 368, at 159-60 ("Federal agencies could release [a "white paper" synthesizing relevant scientific information] as—or in conjunction with—the preamble to a formal notice of proposed rulemaking, as has been done for major regulations by the [FDA] and the EPA."); 59 Fed. Reg. 1638, 1640 (1994) ("In addition [to labeling], FDA uses consumer education vehicles such as the *FDA Consumer* magazine to inform the public about issues concerning misuse of ornamental ceramicware to avoid lead exposure from this source."); 44 Fed. Reg. 59,509, 59,514 (1979) (in issuing its final rule on 4-MMPD, FDA decided that rulemaking proceedings rather than product labeling would provide appropriate forum for debate about true nature of risk).

509. *See supra* notes 273-276 and accompanying text. Furthermore, although FDA does not permit statements of differing opinions in labeling, debates and disagreements about the risks posed by a substance could be discussed more fully in scientific journals and other appropriate public fora. *See* 40 Fed. Reg. 28,582, 28,583 (1975); 39 Fed. Reg. 33,229, 33,231 (1974).

510. 47 Fed. Reg. 39,147, 39,149 (1982) ("The agency is aware of approximately 25 commercially available books that provide readily understandable information about numerous prescription drugs. . . . Virtually all of these publications are available in paperback at a reasonable price. Moreover, such books have the recognizable benefit of providing drug information in a single retainable volume, which the patient can conveniently refer to with each refill of a prescription.")

511. *See, e.g.,* Stenzel, *supra* note 227, at 523-25 (suggesting that product information fliers akin to material safety data sheets used in occupational settings be made available to consumers at retail outlets such as grocery stores). At least one such compilation, published by the Consumer Federation of America, exists at present. *See* STEPHEN BROBECK & ANNE C. AVERYT, *THE PRODUCT SAFETY BOOK* (1983).

512. Unlike educational efforts, warning label requirements are essentially self-perpetuating programs that impose few direct costs on the agency. Sustained public education campaigns undertaken by federal regulators therefore are likely to remain uncommon unless mandated by Congress. *See* Robert S. Adler & R. David Pittle, *Cajolery or Command: Are Education Campaigns an Adequate Substitute for Regulation?*, 1 YALE J. ON REG. 159, 190-91 (1984); Sunstein, *supra* note 382, at 654 ("[O]ur first line of defense should be educative, rather than regulatory. Thus far, we have tended to pursue the opposite strategy—regulate



tion may share some of the same problems as warning labels. Furthermore, disclosure of risk information through publications may trigger overly alarmist media coverage. Unlike warning labels that may not be noticed, the media can cause hysterical public reactions to inconsequential product risks.<sup>513</sup>

### 3. *More Direct Forms of Regulation*

Instead of relying on labeling as the primary response to product hazards, courts and regulators should resort to a warning strategy only after having considered design alternatives or other regulatory options.<sup>514</sup> Regulators sometimes opt for labeling rather than prohibitions to preserve consumers' freedom of choice. Critics have charged that risk communication is a "shield for inaction,"<sup>515</sup> and it is often true that labeling requirements reflect passive responses used to deflect calls for more stringent regulation. Recognizing the temptation faced by regulators when they must grapple with new information about product hazards, the Administrative Conference of the United States cautioned agencies that the "dissemination of risk information [should] not [be] promoted merely as a lower-cost substitute in situations where prescriptive standards might in fact be more appropriate."<sup>516</sup>

If the goal of risk labeling is to encourage consumers to stop purchasing a product, as opposed to encouraging them to make informed choices, the preferred solution would be to ban the product altogether rather than to formulate an overly alarming warning statement.<sup>517</sup> For example, FDA decided to prohibit the use of chloroform as an ingredient in drug and cosmetic products because of new evidence that this widely used substance is an animal carcino-

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first, educate only in exceptional cases.").

513. See Sanford L. Weiner, *Tampons and Toxic Shock Syndrome: Consumer Protection or Public Confusion?*, in CONSUMING FEARS, *supra* note 27, at 158 (arguing that the media oversold relative risk of TSS); *Auvil v. CBS "60 Minutes,"* 800 F. Supp. 928, 930-31 (E.D. Wash. 1992) (describing the "dramatic and swift" public reaction to news story concerning alleged carcinogenicity of Alar, a growth regulator widely used in apple industry); Howard Kurtz, *Stories on Cancer's Causes Are Said to Be Misfocused*, WASH. POST, July 27, 1993, at A6 (survey of news media coverage of carcinogens over last 20 years concluded that relatively minor health risks are exaggerated).

514. See Leslie W. Ball, *Hazard Control by Warnings*, 11 J. PROD. LIAB. 285 (1988).

515. NAS, *supra* note 368, at 96 (quoting Ellen Silbergeld, senior scientist with Environmental Defense Fund).

516. 55 Fed. Reg. 13,538, 13,539 (1990). But see Sunstein, *supra* note 382, at 658-60 (favoring informational remedies over direct regulations on grounds of protecting consumer liberty, increasing market efficiencies, and improving democratic processes).

517. See Viscusi, *supra* note 358, at 290. "Labeling efforts [like Proposition 65] are a disservice to the right-to-know movement. . . . [I]f all risks that consumers are exposed to are stamped as being consequential with no distinctions being made about the severity of the risk, then there will be little or no informational content to the warning program and it will have no beneficial effect on consumer choice." *Id.* at 296; see also STEPHEN G. BREYER, *BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION* 56 (1993).

gen.<sup>518</sup> The Agency rejected comments recommending disclosure of the risk in product labeling so that consumers could retain "the freedom to decide whether to use the product."<sup>519</sup>

Far too frequently, however, decisionmakers seize on risk labeling as the preferred strategy for addressing consumer product hazards. Indeed, warning requirements occasionally represent a surreptitious form of regulation, for instance, to encourage design modifications or product reformulations without directly mandating the desired changes.<sup>520</sup> The CFC warnings required by FDA and CPSC, along with the more recent congressionally-mandated warning for all ozone depleting substances, were intended to increase consumer demand for alternatives during the transition to eventual prohibitions on the use of these substances. If the goal is to influence behavior and deter use of a product without entirely constraining freedom of choice, alternatives to labeling might include special taxes levied on products containing hazardous substances, restrictions on advertising, appropriate age limitations, and prescription requirements of different stringency.<sup>521</sup>

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518. 21 C.F.R. § 700.18 (1993); 41 Fed. Reg. 26,842 (1976); *see also* 21 C.F.R. § 700.14 (1993) (banning vinyl chloride because of acute and chronic risks); *id.* § 700.11 (banning bithionol in cosmetics because of photosensitivity reactions); *id.* § 700.13 (banning most uses of mercury compounds in cosmetics); *id.* § 700.19, 54 Fed. Reg. 27,328, 27,334 (1989) (banning methylene chloride as cosmetic ingredient because estimated lifetime consumer cancer risk exceeded one in ten thousand). Notwithstanding their potential toxicity, mercury compounds may be used as preservatives in cosmetics for use around the eye because of their unsurpassed effectiveness in preventing *pseudomonas* contamination and ocular infection. 21 C.F.R. § 700.13(d) (1993). Although concentration limits are set, the regulation includes no labeling requirements for such products.

519. 41 Fed. Reg. at 26,844; *see also* 52 Fed. Reg. 29,509, 29,513 (1987) (rejecting cautionary labeling as an alternative to a prohibition on interstate sale of raw milk). In a recent proposal addressing hazards from the ingestion of OTC products containing high levels of alcohol, FDA selected maximum concentration limits (depending on age of target user population) rather than a warning statement. 58 Fed. Reg. 54,466, 54,471 (1993) (to be codified at 21 C.F.R. § 328) (proposed Oct. 12, 1993).

520. Although characterized as a "right to know" initiative, the product labeling requirement of Proposition 65 instead appears to have this as its primary goal. *See Gatti, supra* note 229, at 760 & n.136. Similarly, FDA's safety disclaimer for untested cosmetic products, 21 C.F.R. § 740.10(a) (1993) ("Warning—The safety of this product has not been determined."), may have been imposed primarily to encourage manufacturers of these products to undertake necessary testing. Indeed, there appear to be no products currently on the market that include this disclaimer in labeling. Anthony D. Hitchins, *Cosmetic Preservation and Safety: FDA Status*, 57 J. ASS'N FOOD & DRUG OFFICIALS 42, 43 (July 1993).

521. *See Note, Health Regulation of Naturally Hazardous Foods, supra* note 106, at 1046-47 (suggesting prescription or rationing system as an alternative to FDA's ban on swordfish contaminated with mercury); F-D-C REPORTS ("The Pink Sheet"), Feb. 15, 1993, at T&G-2 (describing these options as possible ways of addressing suspected risk of hemorrhagic stroke from weight control products containing phenylpropanolamine); *cf.* 53 Fed. Reg. 21,633, 21,635 (1988) (in extending Reye syndrome warning requirement, FDA rejected suggestions urging "more drastic measures [such as] banning use of aspirin in products for individuals under 21 years of age or limiting such products to prescription use"). One could require that OTC drug products posing certain risks only be dispensed by pharmacists (the so-called "third class" of drugs). *See* 39 Fed. Reg. 19,880, 19,880-81 (1974) (FDA rejection of this idea); Gregory M. Fisher, *Third Class of Drugs—A Current View*, 46 FOOD DRUG COSM. L.J. 583, 597-99, 606-07 (1991) (describing possibility that safety rationales could justify creation of an intermediate class of drugs). Even the availability of prescription drugs could be restricted further if certain serious risks are involved that cannot be avoided adequately through labeling, as is the case with narcotic drugs under the Controlled Substances Act. 21 U.S.C. §§ 811-829 (1988).

#### 4. *Summary*

In short, there are a number of regulatory alternatives available for addressing product hazards. Warning statements should be reserved for those risks that can best be minimized by conveying information in this fashion, whether through instructions for safe use or as a means of risk disclosure to a subpopulation of potential users. For instance, where useful products pose acute risks that are easily avoided by following simple precautionary instructions, labeling is obviously justified. Similarly, if a product poses a serious risk but only to a limited class of consumers (for example, pregnant women), then an appropriate warning statement would be preferable to a prohibition. In other cases, however, superior regulatory alternatives exist if disclosure (for its own sake) or deterrence are the primary goals.

#### Conclusion

The use of warning statements in the labeling of consumer products appears, at first blush, to be a relatively simple and straightforward response to product hazards. Indeed, this evident simplicity has made labeling requirements a preferred option for Congress, federal agencies, state lawmakers, and the courts. When viewed in isolation, many of the warning requirements imposed by each class of decisionmakers seem more or less defensible. Considered in their entirety, however, many of these risk communication efforts appear to be seriously misguided.

It is imperative, therefore, that the primary responsibility for labeling decisions be vested in a single group of decisionmakers. Federal administrative agencies are best suited for this task, and their decisions on the necessity of warnings on labels should preempt state requirements arising under statutory or common law. Congress could express such a judgment through new legislation directed to consumer product labeling generally, or each agency could take the initiative and declare that its warning requirements preempt state law. States would retain the power to impose warning requirements for products not subject to federal regulation, and courts could entertain products liability claims in cases where manufacturers fail to comply with federal or state requirements.

For their part, federal regulators will have to reexamine their own labeling requirements, placing a greater emphasis on selectivity and consistency. To date, agency efforts have been uneven. Better coordination might be achieved through the creation of an interagency task force or working group directed to address these problems. Among the most coherent and comprehensive product warning strategies are FDA's regulation of prescription drug labeling, EPA's control over pesticide labeling, and, to a lesser extent, CPSC requirements for

hazardous substances. Package inserts and pesticide labels convey concrete and balanced information about substantiated risks in a format that organizes this information by level of severity. Ironically, courts have accorded little or no respect to agency judgments about appropriate labeling for these categories of products. As noted above, an essential element of any coherent risk communication system would be the preemption of state requirements.

The real question, however, is whether decisions about the risk labeling of other consumer products can be informed by the approaches used with prescription drugs and pesticides. The same agency that has done such a thoughtful job with package inserts has done a relatively poor job in designing risk labeling for cosmetic products. Although difficulties would arise if consumer labeling were modeled on an approach designed for physicians, agencies and courts could develop improved strategies for communicating risk information to product users. Warning statements should be reserved for those risks that can best be minimized by conveying information through labeling, namely by providing instructions for safe use (to avoid acute hazards) or by serving as a means for disclosing important risk information to a clearly identified segment of potential users. Otherwise, the crazy quilt of warning statements on product labels will continue to grow, at least until courts either penalize manufacturers for diluting serious warnings with trivia or refrain from second guessing federal regulators who have undertaken the difficult task of designing meaningful product labels.